INTERIM REPORT ON THE STUDY OF PATIENT SAFETY IN MARYLAND

EXECUTIVE SUMMARY

During the 2001 session, the Maryland General Assembly passed the "Patients' Safety Act of 2001" charging the Maryland Health Care Commission (MHCC or Commission) with studying the feasibility of developing a system for reducing the incidences of preventable adverse medical events in Maryland, including but not limited, to a system of reporting such incidences. A preliminary report is due to the Maryland General Assembly in January 2002 and a final report in January 2003.

In conducting the study, the Commission is required to review federal reports and recommendations including two reports released by the Institute of Medicine (IOM) titled "*To Err is Human*" (1999) and "*Crossing the Quality Chasm*" (2001). In addition, the Commission must review the recommendations of national accrediting and quality assurance organizations, such as the Joint Commission on the Accreditation of Health Care Organizations (JCAHO) and the National Quality Forum (NQF), as well as programs in other states and the best practices in hospitals and other health care facilities.

Following the release of the first IOM report, private organizations such as the National Patient Safety Foundation and the NQF have developed patient safety data and information in an effort to assist clinicians and educate the public on improving patient safety. Also, the National Academy for State Health Policy (NASHP) has conducted an extensive review of state-level initiatives.

To date, several Federal agencies have issued reports on patient safety recommending evidence-based practices, systemic reforms, and patient safety reporting systems. Federal legislation has also been introduced during the last two years to improve patient safety in various settings; however, no bills have passed. In addition, numerous states have instituted patient safety programs that recommend voluntary and/or require mandatory reporting of adverse events and near misses, or are studying the prospect of reporting such data.

The purpose of this preliminary report is to provide an overview of the current patient safety initiatives in Maryland, other states, the federal government, and public and private organizations. This report also includes a general review of policy issues to be considered when developing a patient safety system. Preliminary recommendations regarding the strategy Maryland should adopt for approaching the issue of patient safety in a time of limited resources as well as an outline of issues to be addressed over the next year are presented as follows:

Preliminary Recommendations

The Patient Safety Initiative in Maryland should build upon existing policies. After reviewing the recent literature on patient safety, surveying major Maryland providers regarding

current initiatives in this area, and discussing future directions with members of the Patient Safety Coalition, the Commission recommends the preliminary strategy outlined below to address legislative requirements of House Bill 1274 "Patients' Safety Act of 2001." The Commission recognizes that most of the recommendations in the Institute of Medicine (IOM) report, such as developing mandatory adverse event reporting and creating centers on patient safety to share best practices, are feasible in the sense that they could be implemented. However, limited resources in the State dictate that Maryland's Patient Safety Initiative instead focus on promoting initiatives that can have the greatest impact for the least cost. Following this reasoning, the Commission proposes achieving systemic change first. As noted in the IOM report, few errors are directly caused by individual providers, but rather are a result of a series of systems failures. Elimination of the potential for errors in the system will have the broadest and most lasting effect. Therefore, MHCC proposes the following:

1) The Patient Safety Initiative in Maryland should build upon existing policies and programs currently in place. The MHCC survey of Maryland facilities and organizations revealed there are currently many state agencies, health occupation boards, associations and facilities actively engaged in patient safety initiatives in each of the areas addressed by the IOM report.

2) Systems – The primary focus of the MHCC study should be on how to promote systemic change within institutions to improve patient safety.

   A) Organizational initiatives to improve patient safety should be prioritized, according to cost and effectiveness. Initiatives to be considered should include:

      1) Automation
         a. Computerized physician order entry (CPOE)
         b. Electronic medical records
      2) Communication (labelings, abbreviations, units, etc.)
      3) Pharmaceutical support
      4) Emergency room (ER) and intensive care unit (ICU) staffing – intensivist
      5) Standardization of orders, common equipment, bar coding, etc.
      6) Team training in patient safety
      7) Simplification

   B) Resources for financing major organizational initiatives such as computerized physician order entry (CPOE), should be explored. Research indicates major initiatives such as CPOE can vary in cost per hospital depending on the size of the hospital. Currently, at least 10 of Maryland's forty-seven acute care hospitals have CPOE or are in the process of implementing it (according to the Maryland Patient Safety Coalition survey). Some hospitals have implemented CPOE in stages to spread the costs. Maryland should take advantage of some of the unique features that exist within the state's health care regulatory structure. The

Commission suggests that the MHCC and the HSCRC collaborate to explore ways to encourage hospitals to adopt systemic improvements either through the rate setting system, the Commission's performance evaluation projects (i.e., consumer report cards), and/or the Certificate of Need process.

C) Increased patient safety can be accomplished by focusing on quality improvement programs and processes. Quality improvement initiatives must be shared across facilities and organizations so that knowledge gained in one place can impact other settings and facilities and reduce potential adverse events even before they occur. This feedback mechanism or sharing of "best practices" should be encouraged and be a main objective of any patient safety system.

D) Organizational leadership within all health care facilities should encourage and promote a culture of patient safety.

E) Efforts to promote systemic change should be expanded beyond hospitals to nursing homes, pharmacies, and outpatient care settings.

3) Regulatory Oversight

A) The initial focus of Maryland's efforts should be on strengthening and improving current patient safety programs already ongoing in Maryland hospitals.

B) DHMH should review and revise current risk management regulations to reflect current expectations.

C) DHMH should explore whether definitions and protocols, including lists of events that need to be internally identified and reported, should be standardized.

D) DHMH should explore the possibility of standardizing reporting requirements under the utilization review program to obtain baseline, aggregate data for certain quality of care issues.

4) Maryland Law

A) Maryland statute should be amended to clarify existing reporting protections for civil immunity that are available to all health care professionals reporting to all health occupation boards and medical review committees. Currently, protections that are available to all health care providers for reporting to medical review committees only appear in the statute governing physicians. Protections should be cited in the statutes of all the health occupation boards.

B) Protections against job loss for those reporting system failures or medical errors jeopardizing patient safety to medical review committees should be explored.

5) The Maryland Patient Safety Coalition should continue to meet to focus on patient safety efforts in Maryland health care facilities and provide clear, visible attention

to patient safety. The Commission should continue to utilize the services of the Coalition as its "sounding board" for discussing pertinent patient safety issues to be explored during the on-going study of potential recommendations to be included in the final report to the General Assembly in January 2003.

In order to develop final recommendations for Maryland's patient safety initiative, due to the Maryland General Assembly in January 2003, the MHCC will explore several issues over the next twelve months. Input on these issues will be solicited from the Patient Safety Coalition as well as national organizations. Questions to be addressed include the following:

1) Should a non-punitive system (blame-free culture) be developed to encourage voluntary reporting of system failures or "near misses" without legal discovery?

   A) Explore requiring institutions to have internal systems to encourage reporting of near misses and aggregated reporting of systemic problems to a private or non-regulatory organization.
   B) Address issues of discoverability/confidentiality in voluntary reporting.
   C) Consider designation of a private or non-regulatory organization to be a Patient Safety Center. Seek federal funds to set up the Center to disseminate information on near misses, systemic remedies, and best practices.

2) How do staffing issues impact patient safety?

   A) Explore whether links exist between staffing and patient safety.
   B) Investigate whether staffing ratios can be meaningfully quantified as they related to quality of care.

3) Should a patient safety system include the mandatory reporting of serious adverse events?

   A) Should a mandatory reporting system include specific adverse events, such as those defined by the National Quality Forum (NQF)?
   B) Should the state require mandatory reporting from all licensed facilities including assisted living facilities and ambulatory surgery centers? How could reporting requirements be enforced?
   C) Should the adverse events required to be reported be publicly disclosed?

4) Should quality assurance programs currently required in hospitals and nursing homes be mandated for other facilities and in other settings as a condition of licensure?

5) What role should State government have in promoting quality improvement especially in view of the relationship between patient safety and quality improvement? Should the State or a private entity assume the role of providing leadership to promote quality improvement within the health care system?

I. Introduction

During the 2001 session, the Maryland General Assembly passed the "Patients' Safety Act of 2001" charging the Maryland Health Care Commission (MHCC or Commission)[1] with studying the feasibility of developing a system for reducing the incidences of preventable adverse medical events in Maryland, including but not limited, to a system of reporting such incidences (see Appendix A).[2] A preliminary report is due to the Maryland General Assembly in January 2002 and a final report in January 2003.

In conducting the study, the Commission is required to review federal reports and recommendations including two reports released by the Institute of Medicine (IOM) titled "*To Err is Human*" (1999) and "*Crossing the Quality Chasm*" (2001). In addition, the Commission must review the recommendations of national accrediting and quality assurance organizations, such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the National Quality Forum (NQF), as well as programs in other states and the best practices in hospitals and other health care facilities.

Following the release of the first IOM report, private organizations such as the National Patient Safety Foundation and the NQF have developed patient safety data and information in an effort to assist clinicians and educate the public on improving patient safety. Also, the National Academy for State Health Policy (NASHP) has conducted an extensive review of state-level initiatives.

To date, several Federal agencies have issued reports on patient safety recommending evidence-based practices, systemic reforms, and patient safety reporting systems. Federal legislation has also been introduced during the last two years to improve patient safety in various settings; however, no bills have passed. In addition, numerous states have instituted patient safety programs that recommend voluntary and/or require mandatory reporting of adverse events and near misses, or are studying the prospect of reporting such data.

The purpose of this preliminary report is to provide an overview of the current patient safety initiatives in Maryland, other states, the federal government, and public and private organizations. This report also provides preliminary recommendations regarding the strategy Maryland should adopt for approaching the issue of patient safety in a time of limited resources as well as an outline of issues to be addressed over the next year.

Throughout this report several terms referring to patient safety are defined consistent with those used in the IOM report. National organizations and federal agencies other than the IOM may define these terms somewhat differently. The following terms are defined by the IOM[3] -

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[1] The MHCC is a 13-member independent commission located administratively within the Department of Health and Mental Hygiene. The Commission is responsible for administering the provisions contained in the Health General Article §§ 19-101 through 19-141. The Commission was created in 1999 by combining the Health Care Access and Cost Commission (HCACC) and the Maryland Health Resources Planning Commission (MHRPC).

[2] Chapter 318 of 2001 (House Bill 1274)

[3] Institute of Medicine. To Err is Human: Building a Safer Health System National Academy Press (Eds. Kohn, L.T., Corrigan, J. & Donaldson, M.S.). 2000.

- Adverse event: an injury or death resulting from medical management rather than the underlying condition of the patient.
- Medical error: the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.
- Preventable adverse event: an adverse event attributable to error.
- Near miss: an error that does not result in harm

II. Maryland Patient Safety Coalition

As part of the enabling legislation, the MHCC is required to review patient safety initiatives in consultation with the Department of Health and Mental Hygiene (DHMH). In developing its preliminary recommendations, the Commission worked with the Maryland Patient Safety Coalition comprised of representatives from the Delmarva Foundation, hospital and insurance industries, as well as the nurses, pharmacy, and medical associations and state health occupation's boards. Members of the Maryland General Assembly were also invited to participate.

The Delmarva Foundation is the Medicare Peer Review Organization (PRO) for both Maryland and Washington, D.C. As such, Delmarva plays a significant role in quality assurance activities in the State. The Patient Safety Coalition serves as a sounding board for Commission's activities related to patient safety. Coalition meetings were held from June 2001 through December 2001. Appendix B provides an overview of the meetings' agendas.

Summary of Coalition activities

Described below are selected excerpts from the Maryland Patient Safety Coalition meetings. These selections are key points discussed during the meetings.

1. State reporting systems -

Representatives from three state agencies outside of Maryland presented information on their state's patient safety reporting systems. New York, Massachusetts, and Pennsylvania maintain mandatory reporting systems of adverse events, each with programs varying as to the type of information collected, the entities required to report, legal protection of the data and use of the data.

The New York Patient Occurrence Reporting and Tracking System (NYPORTS) is a mandatory adverse event reporting system based in statute. The definitions of adverse events are explicitly defined for the health care entities by an 'includes/excludes' list of 54 codes.[4] Information on an adverse event is submitted by an entity on a short form using a computerized reporting system. Entities are not fined for reporting information; however, if the New York

[4] Jill Rosenthal, Maureen Booth, Lynda Flowers, and Trish Riley. *Current State Programs Addressing Medical Errors: An Analysis of Mandatory Reporting and Other Initiatives*. National Academy for State Health Policy.. January 2001.

Department of Health becomes aware of an adverse event that was not reported, the health care entity is fined. A majority of the events are reported using a 'short-form;' patient identification and a narrative description of the incident are required. A small percentage of the reports require root-cause analysis.[5] Hospitals are able to track their performance against a peer group. Hospital aggregate reports, absent patient and provider identifiers, are made public.

In Massachusetts, the Department of Health maintains a mandatory reporting system for defined adverse events. Entities are required to report to the Department immediately by phone for certain events and within seven days for other serious incidents. Information regarding an adverse event is made available to the public if an onsite investigation is warranted. The Massachusetts Coalition for the Prevention of Medical Errors, an advisory board for patient safety, has identified the sharing of best practices and education and training as a short-term goal.[6]

The Pennsylvania Department of Health requires all licensed health care facilities to immediately notify the Department of certain incidents affecting quality assurance or patient safety. This regulation did not take effect until a confidentiality provision was added in 1998. Pennsylvania requires patient and provider identification, type of incident, description of the incident, individual reporting the incident, date the incident occurred, and action taken by the facility. The facility's risk management department forwards this information to the Department of Health for further review. Confidentiality provisions are maintained in regulations.[7] The Department of Health may introduce legislation establishing a system of "near misses" and enhanced legal protection for patients and providers.[8]

2. Maryland state survey on patient safety activities -

Part of the charge requiring the Commission to conduct the study on patient safety necessitates an overview of activities within Maryland health care agencies, associations, hospitals and other health care entities to reduce adverse events. The Coalition developed a survey to capture information on hospital, nursing home, provider and industry association, and state health occupation board current activities in patient safety. These groups were asked to complete the survey listing specific activities instituted by the organization to improve patients' quality of care and to answer questions related to the management and leadership activities devoted to enhancing patient safety. In order to get a complete picture of patient safety activities, it was recommended that organizations obtain input from all appropriate parties, including CEO, Vice President for Medical Affairs, Director of Patient Services, Director of QI and Risk Management, Director of Pharmacy, etc. The survey responses are presented in aggregate in Section VI - Maryland Survey Results (page 21).

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[5] Frederick Heigel, Director, Bureau of Hospital and Primary Care Services Office of Health Systems Management New York State Department of Health. Presentation to the Maryland Patient Safety Coalition. October 11, 2001.

[6] Nancy Ridley, MS., Assistant Commissioner, The Massachusetts Department of Public Health. Presentation to the Maryland Patient Safety Coalition. October 11, 2001.

[7] Jill Rosenthal, Maureen Booth, Lynda Flowers, and Trish Riley. *Current State Programs Addressing Medical Errors: An Analysis of Mandatory Reporting and Other Initiatives*. National Academy for State Health Policy.. January 2001.

[8] Richard H. Lee, Deputy Secretary for Quality Assurance, Pennsylvania Department of Health. Presentation to the Maryland Patient Safety Coalition. November 8, 2001.

3. Survey of hospital risk management plans –

Carol Benner, Director of the Department of Health and Mental Hygiene's Office of Health Care Quality (OHCQ), presented information on hospital risk management plans. Maryland law requires hospitals to have risk management programs that identify incidents, investigate and evaluate incidents in a timely manner, take appropriate action to prevent re-occurrence and have a process to address concerns of patients. Hospitals are protected from civil action in conducting these activities. Maryland law also requires hospitals to have utilization review plans. As part of the utilization review plan, hospitals are required to submit an annual report to the Secretary that includes a listing and description of quality of care problems.[9] The OHCQ investigates complaints about hospitals and subsequently monitors corrective action for any patient care deficiency identified.

In conjunction with the Maryland Patient Safety Coalition activities, the OHCQ requested that all hospitals resubmit and update their Risk Management/Patient Safety Plans. Hospitals were also asked to submit any other relevant materials. Further information is presented in Section V – Maryland's Regulatory System (page 18).

4. Maryland Board of Pharmacy presentation -

In September 2001, a presentation on the Maryland Board of Pharmacy Initiatives in Medication Errors was presented to the Coalition by Jeanne Furman, R.Ph., Commissioner, Maryland State Board of Pharmacy. A Medication Error Task Force was created to identify and prioritize strategies to guide practitioners and permit holders in redesigning medication systems to reduce the incidence and severity of medication errors and to assist the Board of Pharmacy in developing strategies to implement the options the Board selects to address. The Task Force has recommended to the Board several initiatives to reduce medication errors and improve patient safety. They include: educating consumers and practitioners through pamphlets, newsletters, and the Board's website; and using a "systems" approach for medication error complaints. Currently, the Board maintains a non-punitive philosophy for those medication errors that are reported.

Recently, the Board of Pharmacy approved regulations that: define "high-alert medication" and a "medication error;" require pharmacies to establish methods to educate patients in preventing medication errors; require pharmacies to ensure that every staff person involved in the delivery of medications receives, at least once annually, education regarding preventing medication errors; and require pharmacies to establish and maintain a quality assurance program.

5. Review of Maryland state statutes on legal liability protections and continuing education

Frederick Ryland, an Assistant Attorney General for the MHCC, presented information on the State health occupation boards' requirements for continuing education in patient safety, whistleblower protection, and qualified immunity[10] statutes to protect people who report

[9] Code of Maryland Regulations. 10.07.01.19 (7). Acute General Hospitals and Special Hospitals.

[10] Qualified immunity provides protection from civil liability unless in the event of malice. In this context, malice involves making the report with evil intent and the desire to willfully injure the party about whom the report is being made.

substandard care. Mr. Ryland stated that no health regulatory board specifically requires continuing education on patient safety, but patient safety instruction within the confines of an accredited curriculum would be permissible credit for all health disciplines. While the general language of these regulations covering continuing education of health professionals does not expressly require or mandate education on patient safety, the language does not preclude it either. The objective of patient safety is implied in every form of health practice. Thus, while education on patient safety is not directly mandated, course content that includes the topic of patient safety and otherwise meets accreditation standards would qualify for continuing education credit.

In Maryland, no statute requires the reporting of patient safety violations by physicians, but nursing, pharmacy and physical therapy personnel must report potential practice violations to their respective boards, and hospitals must report disciplinary actions against physicians to the BPQA. In Maryland, nurses are compelled to report to the Board of Nursing an action that violates the Nursing Practice Act (Health Occupations § 8-505(a)). In addition, pharmacists (COMAR 10.34.10.05) and physical therapists (COMAR 10.38.02.01F) mandate in their regulations the reporting of practice code violations. For physicians, Maryland requires hospitals, related institutions, and alternative health systems to file periodic reports with the Board of Physician Quality Assurance (BPQA) that state whether a practitioner has been denied privileges or had disciplinary action taken by the facility (Health Occupations, §§ 14-413 and 14-414). With reports compelled under these statues, "qualified immunity" is granted to the maker of the report (Courts and Judicial Proceedings, § 5-715(d)). Reporting to disciplinary boards of patient safety violations implicating health professionals is protected against private litigation by this qualified immunity privilege.

A chart outlining the statutes and regulations pertaining to continuing education and civil immunity protections is presented in Appendix C.

III. Federal/National Initiatives to Promote Patient Safety

Overview

In November of 1999, the National Academy of Sciences' Institute of Medicine (IOM) published a report, *To Err Is Human: Building a Safer Health System,*[11] as a direct result of the *Quality in Health Care in America* project. This report focused public attention on patient safety. The IOM defines patient safety as ***freedom from accidental injury.***

Following the 1999 IOM report, the Government Accounting Office (GAO) was asked by several members of Congress to report on Adverse Drug Events (ADEs). The GAO's findings were published in a report, *Adverse Drug Events.* Both of these publications, the IOM's initial report and the GAO's findings, prompted the creation of several task forces, most notably the Quality Interagency Coordination Task Force (QuIC), which was formed in December, 1999.

[11] Institute of Medicine. To Err is Human: Building a Safer Health System National Academy Press (Eds. Kohn, L.T., Corrigan, J. & Donaldson, M.S.). 2000.

The five major Federal reports dealing with patient safety issues to date in chronological order are:

To Err is Human: Building a Safer Health System. In this report released by the IOM, the agency estimated that up to 98,000 Americans die each year as a result of systemic problems rather than poor performance by individual providers, and outlined a four-tiered approach to prevent medical mistakes and improve patient safety.[12] The four recommendations are: (1) Establish a national focus to enhance knowledge about patient safety; (2) Identify and learn from errors via a mandatory reporting system and encouragement of voluntary systems; (3) Raise standards and expectations through oversight organizations; and (4) Create safety systems. The report concluded that health care is a decade or more behind other high-risk industries in ensuring basic safety.

Adverse Drug Events. A report published by the GAO in response to a request by Congress identified medication-related errors are one of the most common types of errors that account for additional health care costs and disabilities. Drug complications account for 19% of adverse medical events. The report cautions, "The magnitude of health risk [to adverse drug events] is uncertain because of limited incidence data."[13]

Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and their Impact. This report was released by Quality Interagency Coordination Task Force (QuIC) which was charged by President Clinton with responding to the IOM recommendations. The purpose of establishing the QuIC was to coordinate certain federal agencies with an interest in quality health care to explore federal actions to address patient safety. In this report, QuIC responds to each IOM recommendation by outlining Federal actions to achieve the goals set forth in IOM report. In addition, the Task Force proposed additional Federal initiatives to improve patient safety which are not adequately addressed by the IOM, including: building public awareness; building purchasers' awareness; working with providers to improve patient safety; using decision-support systems and information technologies and using standardized procedures; checklists; and the results of human factors research.

Crossing the Quality Chasm: A New Health System for the 21st Century.[14] This is another IOM report as a follow-up to their previous publication, *To Err is Human*. This book is a further call to action to improve the health care delivery system as a whole, in all of its quality dimensions.

Making Health Care Safer: A Critical Analysis of Patient Safety Practices. The Agency for Healthcare Research and Quality (AHRQ) in July 2001, published this report in collaboration with the University of California San Francisco/Stanford University. The publication includes 79 specific practices that contribute to safer patient care and validates each one according to current research. Out of 79 practices, 11 practices with the strongest evidence were rated as the most

[12] Ibid.
[13] United States General Accounting Office. Adverse Drug Events: The Magnitude of Health Risk is Uncertain Because of Limited Incidence Data. January 2000.
[14] Institute of Medicine. Crossing the Quality Chasm: A New Health System for the 21st Century. National Academy Press. 2001.

significant in terms of the strength of the evidence (see Appendix D for the practices). These 11 practices received the authors' support for more widespread implementation.

Federal/National Organizations

Many organizations, federal agencies or Task Forces have been formed to focus on patient safety issues. Diagram A outlines the groups involved.

Advisory Commission on Consumer Protection and Quality in the Health Care Industry

During the Clinton administration, the Advisory Commission on Consumer Protection and Quality in the Health Care Industry was created, "to advise [former-President Clinton] on changes occurring in the health care system at that time and to recommend such measures as may be necessary to promote and assure health care quality value and protect consumers and workers in the health care system."[15] The Commission was comprised of 32 members selected from the private sector. In its very broad summary of recommendations, the Commission set forth several objectives that were aimed at the quality of health care in general. These recommendations addressed providing strong leadership, advancing quality measurement and reporting, creating public-private partnerships, encouraging action by group purchasers, strengthening the hand of consumers, focusing on vulnerable populations, promoting accountability, reducing errors and increasing safety in health care, fostering evidence-based practice and innovation, adapting organizations to change, engaging the health care workforce, and investing in information systems. The Commission also examined evidence of problems in the delivery of quality health care. The areas that were described as examples of gaps in quality were as follows: errors that could be avoided; under-utilization of services; over-utilization of services; and variation in services from one region of the United States to another.

The Institute of Medicine

The Institute of Medicine (IOM) initiated the Quality of Health Care in America project. The initial IOM report, ***To Err is Human*** (1999), focused on patient safety and offered broad recommendations that the IOM Quality of Health Care in America Committee (formed in June 1998) felt would greatly impact the quality of health care. Additional reports were anticipated regarding other quality-related issues. Initial attention concentrated on medical errors, estimating that medical errors result in the deaths of approximately 44,000 to 98,000 Americans yearly.[16] In contrast, an article featured in the *Journal of the American Medical Association* disagreed with the figures cited by IOM. The authors claimed that one of the studies used to approximate the number of patient safety-related deaths did not take into consideration a comparison group and certain confounding factors, as well as other factors.[17] This issue of JAMA also includes a response by a member of the IOM study committee to the aforementioned article.

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[15] President's Advisory Commission. Consumer Protection and Quality in the Health Care Industry. June 1998

[16] Institute of Medicine. To Err is Human: Building a Safer Health System National Academy Press (Eds. Kohn, L.T., Corrigan, J. & Donaldson, M.S.). 2000.

[17] Clement J. McDonald, MD., Michael Weiner, MD, MPH, and Siu L. Hui, PhD. "Deaths Due to Medical Errors are Exaggerated in Institute of Medicine Report." The Journal of the American Medical Association. 284(1). July 5, 2000.

The IOM committee emphasized that a basic level of safety should be assured for all who use the health system and a strong regulatory component is critical to accomplishing this goal. The concept of safety is from the patient's perspective, as is their concept of quality. Defining patient safety as *the freedom from accidental injury* implies an overarching view of safety that has many implications. It is not merely assuring that a patient does not fall, or that the correct limb is operated upon. The IOM report demonstrates to consumers and health care providers that every aspect of the patient's care should be free from harm no matter what the setting. No agency prior to the IOM report considered patient safety in such broad terms.

The report also notes that in addition to the unfortunate health consequences as a result of medical errors, there are direct and indirect costs borne by society as a whole. Direct costs refer to higher health care expenditures, while indirect costs include factors such as lost productivity, disability costs, and personal costs of care. The total national cost associated with adverse events was approximately four percent of national health expenditures in 1996.[18] Figured into the cost was lost income for disabling injuries caused by adverse events, lost household production and actual disability and cost for hospital care.

The report emphasizes that safety does not reside in a person, device or department, but emerges from the interactions of components of a system. Safety is more than just the absence of errors. Safety has multiple dimensions, including the following:

- An outlook that recognizes that health care is complex and risky and that solutions are found in the broader systems context;
- A set of processes that identify, evaluate, and minimize hazards and are continuously improving; and
- An outcome that is manifested by fewer medical errors and minimized risk or hazard.

Ensuring patient safety, therefore, involves the establishment of operational systems and processes that increase the reliability of patient care. These processes include automation, better communication, simplification, standardization, and team training.

The IOM report draws from the experience of other high-risk industries, especially the airline industry. The applicability of the airline industry's procedures to encourage the reporting of adverse events and near misses to expose potential problems is explored, as well as the notion of a blame free culture.

The IOM issued a second report in 2001 titled ***Crossing the Quality Chasm: A New Health System for the 21st Century***. This is the final report of the Committee on the Quality of Health Care in America. This publication addresses quality-related issues to an even broader degree than their first publication, providing a strategic direction for the complete redesign of the health care delivery system. Whereas *To Err is Human* was a call for action, *Crossing the Quality Chasm* calls for a complete redesign of the health care system, as we know it. The "chasm" refers to the gap that exists between today's medical system and an improved, higher quality system.

[18] Institute of Medicine. To Err is Human: Building a Safer Health System National Academy Press (Eds. Kohn, L.T., Corrigan, J. & Donaldson, M.S.). 2000 (p 27).

As a starting point, the Committee proposes six aims for improvement to address key dimensions in today's health care system. According to the Committee, health care should be safe, effective, patient-centered, timely, efficient, and equitable. Secondly, the report lays out ten rules to guide the improvement and re-design care to meet the six aims. These rules were designed with three principles in mind: that care should be evidence-based; patient-centered; and systems-based. The link between each rule and how it might contribute to improved patient safety is clear. One rule specifically calls for "safety as a system property".[19] This dovetails with the recommendations of the previous IOM report and re-emphasizes that safety is tied to the system design and that the culture of blame and fear of punishment should give way to one of system accountability.

In addition, the report recommends that the health care industry sharpen its focus on developing evidence-based approaches to address 10 to 15 of the most widespread "priority" chronic conditions, similar to the Veteran's Health Administration's (VHA) Quality Enhancement Research Initiative (QUERI) namely, cancer, diabetes, hypertension, asthma, emphysema, high cholesterol, ischemic heart disease, HIV/AIDS, and arthritis, gall bladder disease, stomach ulcers, back problems, stroke, Alzheimer's Disease and other dementias, depression, and anxiety disorders. Recognizing that even a focused effort around a small number of chronic conditions will require sizeable resources, the report recommends that Congress establish a $1 billion Quality Innovation Fund. The report also addresses the need to re-tool payment methods, as none reward or encourage quality improvement.

Quality Interagency Coordination Taskforce

Published by QuIC, ***Doing What Counts for Patient Safety*** is a formal "road map" for action. Published very shortly after the IOM report, it lays out an agenda of actions and inventories already-existing Federal activities for carrying out the IOM recommendations. It directs certain organizations such as the NQF, FDA and the AHRQ to perform activities and report back to the committee on their findings. In instances, where QuIC felt there were gaps, they made additional recommendations and offered financial and conceptual solutions. QuIC's report puts the IOM's overarching goals into tangible Federal actions. The Federal agencies that were involved in this project were: the Department of Commerce, the Department of Defense, the Department of Health and Human Services, the Department of Labor, the Department of Veterans Affairs, the Federal Bureau of Prisons, the Federal Trade Commission, the National Highway Transportation and Safety Administration, the Office of Personnel Management, the Office of Management and Budget and the United States Coast Guard. A Compendium of the Federal Action Items is provided in Appendix E.

National Quality Forum (NQF)

NQF's ***Serious Reportable Events in Patient Safety*** attempts to establish agreement on a set of serious, preventable adverse events, which might form the basis for a national, state-based event reporting system and could lead to substantial improvements in the quality of patient care. QuIC charged the NQF with this task. Twenty-seven events have been identified by NQF and are currently under review (see Appendix F).

[19] Institute of Medicine. Crossing the Quality Chasm: A New Health Care System for the 21st Century. National Academy Press. 2001.

The NQF is a private, non-profit organization, created to develop and implement a national strategy for quality measurement and reporting in health care. Established as a public-private partnership, and incorporated in May of 1999, the NQF has a broad participation from all parts of the health care sector, including national, state, regional and local groups representing consumers; public and private purchasers; health care professionals; providers and plans; accrediting bodies; supporting industries; and health care research and improvement organizations.

General Accounting Office

The General Accounting Office (GAO) prepared a report on adverse drug events at the request of Congress. The report describes the different types and causes of adverse drug events (ADEs), the overall incidence and cost of ADEs, and the measures that have been proposed to reduce their number and severity. The IOM had earlier found that, in reviewing U.S. death certificates between 1983 and 1993, 7,391 people had died in 1993 from medication errors (accidental poisonings by drugs, medications and biologicals that resulted from acknowledged errors by patients or medical personnel). These and other medication-related errors occur frequently in hospitals.[20]

In the report, the GAO found that the risk of ADEs has multiple factors. Some adverse drug reactions (ADRs) are the predictable result of a drug's known pharmacological properties. Some patients have a greater risk of ADRs than others. Patients themselves may also contribute to ADEs by noncompliance with medical instructions. The GAO concludes by outlining some of the current and proposed main categories of approaches to reduce medication errors. The major categories of change include: (1) Changes in dispensing; (2) Changes in packaging and physical characteristics; (3) Change in sensitivity to ADEs, by education, communication, etc.; and (4) Change in culture.

The Joint Commission on the Accreditation of Health Care Organizations (JCAHO)[21]

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is the nation's oldest and largest accrediting body for health care organizations. They accredit over 19,000 organizations that provide a wide range of services. The process by which hospitals and other health care facilities undergo accreditation by JCAHO involves announced triennial on-site surveys performed by surveyors who are qualified to evaluate an organization's compliance based on applicable standards that have been developed in consultation with health care experts. Surveyors evaluate compliance with each of the applicable standards using a five-point scoring scale.

Currently in Maryland, all hospitals are accredited by JCAHO and have been granted "deemed status" by the federal Centers for Medicare and Medicaid Services (CMS) and Maryland's Department of Health and Mental Hygiene (DHMH). This means that hospitals accredited by JCAHO meet state licensure requirements and federal Medicare and Medicaid certification requirements. In essence JCAHO acts as an "agent" for CMS surveys. In addition,

[20] United States General Accounting Office. Adverse Drug Events: The Magnitude of Health Risk is Uncertain Because of Limited Incidence Data. January 2000.
[21] Joint Commission on Accreditation of Healthcare Organizations. http://www.jcaho.org.

JCAHO must provide CMS with a listing of organizations and their accreditation status – Accreditation without Type I Recommendations (becomes Accreditation with Full Standards Compliance – January 1, 2002), Accreditation with Type I Recommendations (becomes Accreditation with Requirements for Improvement – January 1, 2002), Provisional Accreditation, Conditional Accreditation, Preliminary Denial of Accreditation, Accreditation Denied, and Accreditation with Commendation - as well as accreditation decision reports involved in CMS validation surveys and any other survey report CMS requests. Federal "deemed status" does not provide an exemption from current requirements for state licensure; however, Maryland relies on JCAHO for a large portion of its hospital oversight activities.

In 1996, JCAHO created a hospital sentinel event reporting system. Sentinel events subject to reporting are those that have resulted in an unanticipated death or major permanent loss of function not related to the natural course of the patient's illness or underlying condition, or an event that meets the following criteria (even if the outcome was not death or major permanent loss of function): (1) suicide of a patient in a setting where the patient receives around-the-clock care; (2) infant abduction or discharge to the wrong facility; (3) rape; (4) hemolytic transfusion reaction involving the administration of blood or blood products having major blood group incompatibilities; or (5) surgery on the wrong patient or wrong body part. JCAHO requires that a hospital that experiences a sentinel event conduct a "root cause analysis," a process for identifying the basic or causal factor of the event that underlie variation in performance. A root cause analysis focuses primarily on systems and processes, not individual performance. It progresses from special causes in clinical processes to common causes in organizational processes and identifies potential improvements along the "route" that would tend to decrease the likelihood of such events in the future, or determines, after analysis, that no such improvement opportunities exist. The product of the root cause analysis is an action plan that identifies the strategies that the organization intends to implement to reduce the risk of similar events occurring in the future.

Accredited organizations are encouraged, but not required to report to JCAHO any sentinel events meeting the above criteria. If an organization voluntarily reports to JCAHO, JCAHO may not take any action to jeopardize the health care entity's accreditation status. However, if the Joint Commission becomes aware of the sentinel event by some other means, an organization may be required to prepare a thorough and credible root cause analysis and action plan within 45 calendar days of the event. The Joint Commission then determines whether the root cause analysis and action plan are acceptable. If the root cause analysis is not acceptable, the organization is at risk for being placed on Accreditation Watch by the Accreditation Committee. Particular aspects of this policy are currently under review.

The Veterans Health Administration, Department of Veterans Affairs (VA)

The Veterans Health Administration (VHA) is broadly acknowledged as a model for those health systems that want to improve patient safety. The $20 billion VHA is the nation's largest integrated hospital and health care system. It includes 173 medical centers, approximately 800 outpatient clinics, 134 nursing homes, 206 counseling centers, and assorted other programs.[22] The VA employs 200,000 people, and more than three million veterans a year seek medical services at VA hospitals. A series of fatal medical errors at VA hospitals documented in

[22] The Veterans Health Administration. http://www.va.gov/About_VA/Orgs/VHA/index.htm.

the *St. Petersburg Times* followed by an internal report and a series of GAO reports that led to Congressional hearings propelled the VA to action. The VA pledged to Congress that they would wage an all-out campaign against medical errors. [23] The VA's efforts to uncover mistakes were aided by health care providers' immunity from legal liability. Under the Federal Tort Claims Act, retired members of the armed forces or their immediate family members can legally file a claim for medical malpractice against the United States. Unlike malpractice claims against private providers, the United States government defends individual Veterans Administration practitioners acting within the scope of their employment.[24] This protection has made it noticeably easier for the VA to encourage error reporting.

In 1998, the National Center for Patient Safety was created within the VHA in an effort to improve the system of care through "processes that identify, prevent, and fix problems that result medical errors."[25] Four VA centers were designated Patient Safety Centers of Inquiry the following year. Each was to receive $1.5 million over the next three years to conduct research and identify safety techniques and technologies other industries are using and that may have health care applications.

Other initiatives include the institution of a bar-coding system within certain VA hospitals. According to the VA, bar coding is a relatively low-cost, high benefit safety improvement used to manage patients' medications. As of 2000, the bar coding system is used in 170 VA hospitals.[26] A second innovation was to revise its medication storage procedure. Physical restraint use, which causes an estimated 100 deaths a year in the VA system, was also a safety target. Strengthening the scientific basis of error reduction was a priority. The revamping of the VA's voluntary error data repository, known as the Safety Events Registry (SER), also bolstered their patient safety initiative.

In May 2000, a VA Patient Safety Reporting System was modeled after the aviation industry's reporting system. The voluntary, confidential reporting system is designed to encourage health care providers within the VA health care system to report adverse events and near misses. The reporting system is a three-year project costing $8.2 million.

Other patient safety initiatives include the use of root-cause analysis for reportable events, computerized medical records, and provider continuing education requirements in patient safety.

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[23] Institute for Healthcare Improvement and National Coalition on Healthcare. "Reducing Medical Errors and Improving Patient Safety: Success Stories from the Front Lines." February 2000.

[24] Active duty members of the US Armed Forces cannot file a claim against the federal government under the Federal Tort Claims Act, however, their immediate family members can legally file suit.

[25] Veterans Administration. Health Benefits and Services. Taken from the *Veterans Health Administration Nightlights*. September 7, 2001.

[26] Rhonda L. Rundle. "In the Drive to Mine Medical Data, VHA is the Unlikely Leader" (Vital Signs). The Wall Street Journal. December 10, 2001.

The Department of Health and Human Services (HHS)

The Agency for Healthcare Research and Quality

The Agency for Health Care Research and Quality (AHRQ) published ***Making Health Care Safer: A Critical Analysis of Patient Safety Practices***[27] following the 1999 release of the Institute of Medicine's report. AHRQ commissioned the University of California at San Francisco (UCSF) and Stanford University's Evidence-Based Practice Center (EPC) to review the scientific literature about safety improvement. The charge to the EPC was three-fold: (1) review the existing evidence on practices relevant to improving patient safety; (2) present those findings to the Safe Practices Committee of the Quality Forum (NQF); and (3) grade the practices on the strength of the evidence and the need for further research. Of the 79 patient safety practices reviewed in detail, 11 were most highly rated on the strength of the evidence (see Appendix D).

Several procedures long advocated by safety experts were omitted from the list, such as computerized physician order entry systems to decrease medication errors and changes in nursing staffing patterns to decrease mortality, because of the lack of patient safety research that quantifies the cost, complexity and current utilization of these practices.

In addition, AHRQ recently awarded $50 million in research grants on patient safety and medical error reduction. The projects were awarded to states with existing medical error reporting systems, universities, and health care entities across the country. Also, the HHS Patient Safety Task Force was created in April 2001 to coordinate existing data collection activities of AHRQ, CDC, FDA, and the Centers for Medicare and Medicaid Services (CMS). One goal of the Task Force is to coordinate reporting systems, such as the CDC's National Nosocomial Infections Surveillance (NNIS) system and FDA's reports on adverse events. AHRQ will also promote evidence-based systems for reducing errors.[28]

The Centers For Disease Control and Prevention

The Centers for Disease Control and Prevention (CDC) has a system for reporting nosocomial infections, or hospital-acquired infections. The National Nosocomial Infections Surveillance (NNIS) is a voluntary, hospital-based reporting system established to monitor hospital-acquired infections and to guide the prevention efforts of infection control practitioners. NNIS began in 1970 with 62 participating hospitals in 31 states. By 1999, 285 hospitals in 42 states participated in NNIS. All NNIS hospitals have 100 or more beds and tend to be larger than other U.S. hospitals. Infection control practitioners receive 28 hours of training at CDC and are invited to attend a biennial conference. Infection control practitioners are periodically surveyed to determine their number and spectrum of activities. The CDC recommends that hospitals should have at least one full-time infection control practitioner for every 250 occupied hospital

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[27] KG Shojania, BW Duncan, KM McDonald, et al., eds. Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment No. 43 (Prepared by the Unviersity of California at San Francisco-Stanford Evidence -based Practice Center under Contract No 290-97-0013), AHRQ Publication No. 01-E058, Rockville, MD: Agency for Healthcare Research and Quality. July 2001.

[28] United States Department of Health and Human Services, Agency for Healthcare Research and Quality. *Patient Safety Task Force Fact Sheet*. http://www.ahrq.gov/qual/taskforce/psfactst.htm.

beds.[29] The CDC in conjunction with the FDA manages the vaccine adverse event reporting system (VAERS).

The United States Food And Drug Administration

The Food and Drug Administration (FDA) forms a vital part of the network currently in place for the reporting of adverse medical events. The agency closely monitors marketed human medical products for unexpected events as a part of its postmarketing surveillance. This surveillance is conducted soon after medical products receive FDA approval for distribution.

The Food and Drug Administration host several reporting systems including, MedWatch, Adverse Event Reporting System (AERS), the Drug Quality Reporting System, and the Center for Biologics Evaluation and Research (CBER). The CBER maintains an error and accident reporting system, the Vaccine Adverse Event Reporting System (VAERS), the Manufacturer and User Device Experience (MAUDE) Database and a reporting system for blood and blood components.

The FDA receives reports of suspected adverse events (as defined by the FDA) from manufacturers (required by law and regulation to report to FDA), from user facilities, and from health care professionals or consumers. Under the MedWatch program, health care professionals and consumers are encouraged to report serious adverse events and product problems to the FDA, the manufacturer, or both. MedWatch has established four methods which to report to the FDA, phone (via a toll-free number), fax, direct mail (using a postage-paid form), and Internet (via the interactive form on the MedWatch website). FDA's adverse event database for drugs and therapeutic biological products, the Adverse Event Reporting System (AERS), contains approximately 2 million reports. In FY 1998, more than 230,000 reports of suspected adverse events were received by AERS. The FDA evaluates reporting data from AERS to identify any serious, rare, or unexpected adverse events or an increased incidence of events.

In 1990, amendments to the Safe Medical Device Act (SMDA) expanded FDA's authority by requiring that user facilities (e.g., hospitals and nursing homes) report device-related serious injuries to the manufacturer and device-related deaths to the manufacturer and directly to the FDA. Reportedly 80,000 to 85,000 device-related serious reports are submitted to the FDA each year. The Manufacturer and User Device Experience (MAUDE) database was established in 1995 to support the SMDA. The advantages of this reporting system are that the reports are triaged by medical professionals. Action is taken according to specified criteria, including: the unexpectedness and seriousness of the event, the vulnerability of the population, and whether or not the event was preventable. The analysts' experience and familiarity with the products make this system unique.[30]

In addition, HHS recently announced a proposal requiring all medications administered in hospitals to carry bar codes. The bar codes would feature the medications' properties and

[29] CDC.MMWR. Monitoring Hospital-Acquired Infections to Promote Patient Safety – United States, 1990-1999. March 03, 2000

[30] U.S. Department of Health and Human Services, Food and Drug Administration. *Managing the Risks from Medical Product Use: Creating a Risk Management Framework*. May 1999.

expiration dates. Before the requirement is to take effect, a draft of the proposal will be published through the FDA followed by public comment.[31]

Congressional Action

Several bills have been in introduced in both the Senate and the House of Representatives related to patient safety. The 106th Congress was responsible for approximately six bills having to do with patient safety issues. The 107th Congress has introduced nine bills to date. The subjects include, but are not limited to, the description and requirements of various reporting systems, the establishment of a patient safety center within AHRQ, informatics grant programs to hospitals and skilled nursing facilities, the public disclosure of clinician staffing and performance or outcomes data, the provision of programs to improve nurse retention, and provisions to limit the number of mandatory overtime hours a nurse may be required to work. More detailed information on specific Senate and House bills is provided in Appendix G**.**

Private Initiatives

The Leapfrog Group

The Leapfrog Group is a consortium of approximately 80 Fortune 500 companies and other large private and public health care purchasers. In November 2000, the Leapfrog Group initiated a national effort to recognize and reward providers for advances in patient safety and to educate employees, retirees, and families about the importance of hospitals' efforts in this area. The current focus on improving patient safety is tailored to three areas: computerized physician order entry; evidence-based hospital referral; and intensive care unit physician staffing.

Pittsburgh Regional Health Care Initiative (PRHI)

Similar to the Leapfrog Group, the PRHI was formed to improve health care delivery through specific initiatives. The coalition was formed under the leadership of the former chairman of Alcoa, an aluminum manufacturer. The coalition includes 32 hospitals, four insurers, and over 30 larger and small health care purchasers. [32] The coalition's focus is on improving the health care system by improving outcomes in five areas: cardiac surgery; hip and knee replacement surgery; repeat cesarean sections for women at low risk; depression; and diabetes. In addition, PRHI's aim is to reduce hospital-acquired (nosocomial) infections and medication errors to zero. Data on medication errors are collected through the MedMarx data tracking system (U.S. Pharmacopeia). Nosocomial infection data are tracked through the National Nosocomial Infection System with assistance from the CDC.

These data will be used to benchmark each hospital's improvement in outcomes over time. In support of this initiative, The Robert Wood Johnson Foundation has contributed a $1 million grant.[33]

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[31] Associated Press. “U.S. Considers Prescription Bar Codes.” Milwaukee Journal Sentinel. December 2, 3001.
[32] Kenneth T. Segel. "A New Model for Healthcare Delivery." www.smc.org. July/August 2001.
[33] Jane-Ellen Robinet. "Pittsburgh's Health Care Initiative in National Spotlight." Pittsburgh Business Times. http://pittsburgh.bcentral.com. May 31, 2001.

U.S. Pharmacopeia

U.S. Pharmacopeia is a non-profit, volunteer-based, private organization that works closely with health care practitioners and institutions, regulatory agencies, professional organizations and the pharmaceutical industry to provide education about patient safety. U.S. Pharmacopeia's (USP) MedMARX is a national, Internet-based, interactive medication error prevention tool that enables hospitals using MedMARX to anonymously report and track medication errors in a standardized format. Approximately 250 hospitals use this system, including the Department of Veterans Affairs and the Department of Defense. The system allows the participating facilities to not only report medication errors anonymously, but to retrieve data for their own facility and obtain non-identifiable comparative information on other participating hospitals. An e-mail system allows USP to communicate with users and for users to communicate with USP, while still remaining anonymous by the use of a facility identifier. USP can issue alerts to a single user or a group. Another feature of the MedMARX system is that it also provides a template for the Joint Commission's model for conducting a root cause analysis.

Another reporting system, the Medication Errors Reporting (MER) system, is administered by USP. This system was designed for individual practitioners to report medication errors using an internet-based tool.

The National Patient Safety Foundation

The National Patient Safety Foundation (NPSF) was developed by the American Medical Association in response to the patient safety movement. The mission of the group is to improve patient safety though a core body of knowledge and pathways to apply that knowledge; improve the culture of awareness towards patient safety; and educate the public. The NPSF has issued several grants in an attempt to foster research identifying the underlying safety problems and causes of those problems. The NPSF supports that patient safety should focus on the system of preventing medical errors, and not on individual providers. The NPSF has issued two publications assessing patient safety studies that are currently underway or that have been conducted.[34]

IV. State Initiatives

Following the release of the IOM report (1999), the National Academy for State Health Policy (NASHP) (with support from the California Healthcare Foundation) conducted a survey of the 50 states and Washington, D.C. in an attempt to determine which states employ a reporting system of serious adverse events in hospital settings.[35] NASHP is a non-profit, multidisciplinary forum designed to assist state health policy leaders from the executive and legislative branches on various health policy issues. NASHP conducts policy analysis, provides training and technical assistance to states, produces informational resources, and convenes state, regional, and national forums.

The major findings from the 2000 survey indicated that a universal definition of medical error and adverse event does not exist. Many of the states with existing reporting systems use

[34] "Lessons in Patient Safety" and "Current Research on Patient Safety in the United States." http://www.npsf.org.
[35] Jill Rosenthal, Trish Riley, Maureen Booth, National Academy for State Health Policy, *State Reporting of Medical Errors and Adverse Events: Results of a 50-State Survey*, April 2000.

different definitions to describe an adverse event. Moreover, states with reporting systems differ in their use of the data and whether information reported is publicly disclosed or confidential. Among the survey findings:

- 15 states have mandatory reporting of general and acute care hospitals while 13 states (of the 15) require ambulatory surgical facilities (ASFs) to report and 12 states mandate reporting by psychiatric hospitals;
- Voluntary systems are used in five states and Washington, D.C.;
- As of April 2000, six states had legislation mandating reporting of medical errors or adverse events that did not pass (Iowa, Kentucky, Maine, Missouri, North Dakota and New Hampshire);
- Thirteen of the states that require mandatory reporting have some protection for reports from legal discovery. The type of information and reports that are protected among these states vary;
- Most states have protection for reports at the time they are filed, compared to seven states where reports are protected during the investigation and four states that offer protections after state action. In the event of a request for information under the Freedom of Information Act, five states protect the data, whereas three states do not have protections.
- Seven states have protections in place to prevent access to personally identifiable reports. A promise of confidentiality is provided in five states. Other methods to protect data include anonymous reporting, and removing certain identifiers (i.e., provider names and patient names);
- Reporting of information by the providers is, in most states, encouraged by guaranteeing confidentiality or through education and training of the providers; and
- Among those states with mandatory reporting, definitions of reportable incidents vary.

In addition, in 2001, 21 states introduced patient safety legislation. Six of these states passed laws requiring either patient safety studies or improved quality assurance activities (Connecticut, Indiana, Maryland, Minnesota, Nevada, and West Virginia).[36] As of August 1, Minnesota allows hospitals to participate in a standardized incident reporting system to identify and analyze trends in medical error and iatrogenic injury. Patient identifying information will be redacted.[37] A bill was enacted this year in West Virginia prohibiting discrimination and retaliation against a health care professional because the worker reported an instance of wrongdoing or waste, advocated on a patient's behalf, and/or participated in any investigation relating to the care, services, or conditions of a health care facility.[38] In addition, the health care professional's identity is confidential unless otherwise specified.[39]

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[36] Damon Adams, "State Error Legislation Gets Mixed Reviews." amednews.com. www.ama-assn.org. July 30, 2001.

[37] Minnesota Legislature. 82nd Legislative Session (2001-2002). S.F. No. 560.

[38] West Virginia H.B. 2506, 2001

[39] Ibid. The bill states that "The identity of a health care worker who complains in good faith to a government agency or department about the quality of care, services, or conditions of a health care entity or waste or wrongdoing by the health care entity shall remain confidential and may not be disclosed by any person except upon the knowing written consent of the health care worker and except in the case in which there is imminent danger to health or public safety or an imminent violation of criminal law." §16-38-5.

Mandatory and voluntary reporting systems coexist in many states today, complement each other and assist in the effort to reduce medical errors. The first IOM report recommends a nationwide mandatory reporting system to collect standardized information about adverse events that result in death or serious harm. Mandatory reporting systems are designed, in general, to hold health care organizations accountable for patient safety and in some instances, inform the public. The collected data are used in most states to identify trends, followed by issuing sanctions, assuring corrective action and the issuing of public reports. Massachusetts and Ohio use the data to develop quality improvement projects.

The initial IOM report also encourages voluntary reporting systems for systemic failures and near misses to identify problems before harm occurs. This system is accompanied by a "blame-free culture" in which health care practitioners are rewarded rather than fault being assigned.

As mentioned in the NASHP report, "...reporting systems are not ends unto themselves."[40] The IOM report emphasizes that most errors occur because of system failures. It is noted, however, that providers committing egregious errors must be held accountable for their actions.

V. Maryland's Regulatory System

In DHMH, the *Office of Health Care Quality* (OHCQ) licenses or certifies various health care facilities and services in Maryland. The Hospital Unit within the OHCQ is required under statute to evaluate all hospitals and investigate and respond to all consumer complaints. While this unit is responsible for the licensure and certification of hospitals participating in Medicare, all acute care hospitals have received "deemed" status through JCAHO. The federal government "deems" or grants hospital approval for participation in the Medicare program if the hospital has received JCAHO accreditation. Many states grant a similar "deemed" status to hospitals that replaces the annual review of hospitals and grants them licensure status. Because of this status, Maryland hospitals are not routinely surveyed by the OHCQ, unless a specific situation, such as a complaint, warrants such a review. JCAHO surveys accredited hospitals every three years.

Hospitals do have in-house procedures for reviewing medical problems.[41] Section 14-501 of the Health Occupations Article provides that a medical review committee can investigate problems in a confidential manner (with some exceptions).[42] Anyone reporting an incident to a medical review committee has civil immunity. Although hospitals are not required to submit this information to the OHCQ, some may voluntarily choose to do so. In these cases, the OHCQ triages the problem to determine if an investigation is necessary. The OCHQ may also initiate an

[40] Ibid, p14

[41] Health-General Article, §19-319 (g)(1). As a condition of licensure, each hospital shall establish a risk management program.

[42] Health Occupations Article, §14-501. A civil action brought by a party to the proceedings of the medical review committee who claims to be aggrieved by the decision of the medical review committee; or (2) Any record or document that is considered by the medical review committee and that otherwise would be subject to discovery and introduction into evidence in a civil trial.

investigation based on information received from a patient, a family member, the media, or the federal government. If appropriate, the OHCQ will notify the JCAHO and conduct a joint investigation.

Maryland nursing homes are surveyed by the OHCQ at least twice per year (more inspections may occur if there are deficiencies or complaints), while ambulatory surgical facilities are surveyed once every three years. Ongoing assessments of a nursing home resident's condition are conducted through the Resident Assessment Instrument (RAI), mandated by federal law to be completed for all nursing facility residents at admission and at regularly scheduled intervals. The minimum data set (MDS) portion of the RAI captures the resident's physical and cognitive status, acute medical condition, nutritional status, and behavioral and emotional status. This type of information often identifies the level of quality of care delivered within a facility. MDS data are submitted to the state MDS data repository, then to a national databank.

Recently, the OHCQ initiated a system of "clinical alerts." These are transmittals to hospitals, nursing homes, and other facilities that focus on problematic patterns and trends identified through surveys and investigations. The first clinical alert focuses on anticoagulant therapy and the use of Coumadin. The second alert will focus on end-of-life care.

A complete list of all health care providers regulated by the OHCQ is provided in Appendix H**.**

Although the majority of hospital monitoring has been delegated to the JCAHO,[43] Maryland has always been concerned about patient safety. In 1986, the Maryland General Assembly passed SB560 (Health General Article, Section 19-319(g)(1)) requiring hospitals to have risk management (or quality assurance) programs that include:

(i) A board policy statement indicating commitment to the risk management program;

(ii) A requirement that one person be assigned the responsibility for coordinating the program;

(iii) An internal staff committee structure to conduct ongoing review and evaluation of risk management activities;

(iv) A formal written program for addressing patient complaints;

(v) A documented facility-wide risk reporting system;

(vi) Ongoing risk management education programs for all staff; and

[43] Health-General Article, §§19-308 and 19-309 limit DHMH authority to inspect accredited hospitals. The initial law was passed in the early 1980s. More recently, the General Assembly has acted to expand DHMH authority. In 1995, DHMH was given authority to inspect all complaints; in 2001, DHMH was given authority to monitor any serious problem in a hospital and, if necessary, to impose sanctions.

(vii) Documentation that the risk management and quality assurance programs share relevant information.

DHMH implemented regulations (COMAR 10.07.01.25) on January 1, 1988 to further define risk management programs. The regulations state that these programs are to provide a safer environment for hospital patients through a hospital-wide internal incident identification, reporting, evaluation and corrective action process. All hospitals complied with the new requirement and submitted risk management plans to DHMH for approval.

Although DHMH does not routinely survey hospitals (Maryland law limits routine surveys to non-accredited hospitals only), when surveyors investigate complaints, they routinely evaluate Quality Assurance and Risk Management programs. When problems have been identified, such as a lack of internal incident identification or inadequate problem evaluation, deficiencies are written and the hospital is required to submit a plan of correction.

After the 1999 IOM report and the renewed interest in patient safety on the national level, JCAHO developed new Patient Safety and Medical Error Reduction Standards for all accredited hospitals. These new requirements, effective July 1, 2001, require accredited hospitals to provide a safer environment for hospital patients through an internal hospital-wide occurrence (anything from a "slip or near-miss" to a sentinel event) identification, reporting, evaluation and corrective action process. JCAHO also requires specific mechanisms for determination of severity of an occurrence, mechanisms for the level of response for an occurrence including care of the affected patient, containment of risk and preservation of factual information for subsequent analysis, and notice to patients and families when an incident occurs.

In the Fall 2001, DHMH asked all hospitals to resubmit and update their Risk Management/Patient Safety Programs. Hospitals were also asked to submit any other relevant materials. As of December 1, fewer than half of the 47 acute hospitals had responded. According to OHCQ, an analysis of the information received demonstrates that:

- Plans are fragmented. In many cases, there is a Risk Management Plan for the State, a separate plan for the JCAHO, and even another plan to reflect current practice.
- Language within an organization is inconsistent. Even within one hospital, "events" can be called incidents, occurrences, sentinel events or adverse outcomes. Definitions of each of these may be the same with a different mechanism to address the issue.
- There is little triaging of "events" into levels of harm as required by JCAHO.
- Internal reporting by staff is passive. Rather than active statements indicating who must report, what must be reported, when occurrences must be reported and how, most plans state "Any adverse outcome shall be reported to the risk manager…"
- So far, only one of the plans includes a procedure for adverse event notification to patient or family.
- In many hospitals, the sentinel event policy is verbatim from JCAHO standards and is limited to rape, infant abduction, blood transfusion reaction, wrong side surgery or

suicide. Hospitals have not considered the frequency or types of occurrences unique to the types of services delivered and adjusted the patient safety program accordingly.

- In many cases, the Risk Management/Patient Safety program administratively reports to the Chief Financial Officer indicating that the focus of the program is risk reduction rather that patient safety.

To address these issues, DHMH is working with the MHA. An education program was held on November 8, 2001 where the issues were presented to hospital quality improvement staff. After the analysis of the hospital risk management programs is complete, DHMH will work with the appropriate parties to update the regulations to reflect current patient safety standards and expectations.

Health occupation boards are another arm of State government responsible for licensing and disciplining specific health professions. While these boards are self-supporting in Maryland, they are administratively located in DHMH.

VI. Maryland Survey Results

Overview:

As previously mentioned (in Section II, pp 3 and 4), the Patient Safety Coalition developed and distributed a survey to Maryland hospitals, nursing homes, provider and industry associations, and state health occupation boards in an effort to gain an overview of current patient safety activities within these health care facilities or groups to reduce adverse events (see Appendix I). These entities were asked to complete the survey listing specific activities instituted by the organization to improve patients' quality of care and to answer questions related to the management and leadership activities devoted to enhancing patient safety. In order to get a complete picture of patient safety activities, it was recommended that organizations obtain input from all appropriate parties, including the CEO, Vice President for Medical Affairs, Director of Patient Services, Director of QI and Risk Management, Director of Pharmacy, etc.

The surveys were distributed to 70 hospitals (acute and specialty), 243 post-acute or long-term care facilities, and to a number of associations and health licensing boards. The deadline was November 9, 2001. As of December 3rd, 43 hospitals (36 acute-care), 75 long-term care facilities, and some of the associations and boards submitted completed surveys. Note that the number of responses to the survey may vary depending on each respondent's interpretation of the patient safety issues. Based on the complexity of the data and the variety of initiatives undertaken by the facilities, the Commission recommends that additional analysis be conducted before reporting the data in detail. In addition, those facilities that did not complete the survey should be provided an opportunity to complete it so that a more representative sample of facilities may be obtained.

A preliminary analysis of the data indicates that health care facilities and organizations have undertaken various initiatives aimed at improving patient safety and reducing adverse events. Many of the organizations, especially hospitals, have instituted a cadre of initiatives, ranging from task forces to medication error reduction activities. Over half of the hospitals and

long-term care facilities responding to the survey indicate that a self-assessment has been conducted within the organization to identify processes that need to be improved. A majority of the patient safety activities listed by hospitals are aimed at preventing falls, medication safety, and implementing a patient safety plan and policy. Specific examples of patient safety activities initiated by hospitals include medication-error prevention processes such as removing dangerous drugs from units, the use of special packaging and labeling of high risk drugs, and bar coding of medications and patient identification bracelets. Also, several hospitals have formed task forces to analyze patient safety issues as well as specific clinically related areas of high risk, such as nosocomial infection rates.

Among the long-term care facilities, activities range from risk management projects such as implementing a plan for patient falls, a quality assurance/quality improvement program to a medication error reduction program. One facility listed a medication error reporting system as an initiative, while another facility has a 'zero-accident culture' safety committee. Many of the long-term care facilities that responded to the survey indicate a strong focus of their leadership in identifying, monitoring, and analyzing adverse events.

Very few of the facilities have CPOE and bar coding systems in place to identify and reduce medication errors, while a small number of facilities indicated that they are in the process of implementing these systems. Many of the responses from the hospitals indicate that CPOE, bar coding, simulation, and to some extent, the use of intensivists, has been discussed; however, implementation of these programs has not occurred. These system-wide initiatives are expensive to implement. The availability of resources to fund these activities should be explored further. While the initial cost of implementing these projects is relatively large, it is suggested that the amount of money saved by reducing adverse events and patient length of stay, as well as the increasing the number of lives saved, far outweighs the costs of implementing these projects.

The initiatives undertaken by the responding hospitals and long term care facilities appear to be diverse. For example, educational programs aimed at orienting a new employee or staff member to a facility's patient safety plan or policies are conducted by only a few facilities. The sharing of "best practices" is only fostered by a few facilities as well. While the implementation of the various patient safety activities among the Maryland facilities is particularly noteworthy, the presence of an overall goal or policy among many of the facilities is not always present.

The following analysis of the survey data is presented in accordance with the recommendations listed in the IOM report, *To Err is Human*.

A. Leadership and Knowledge

IOM Recommendation -

The IOM recommended the creation of a federal Center for Patient Safety to set goals for patient safety and evaluate the progress of the goals, develop a research agenda, and develop and distribute best practice information.

While this center has not been created within the federal government, the VA has instituted the National Center for Patient Safety to integrate and direct the VA's patient safety efforts. Since the release of the report, the DHHS has created the Patient Safety Task Force to coordinate existing and planned reporting systems within the AHRQ, CDC, FDA, and CMS. Currently, each of these agencies operates data collection systems that collect data on quality of care measures. In New York, best practices are shared with hospitals using information collected from their mandatory reporting system.

Maryland Survey Results -

The overarching goal of this IOM recommendation is to coordinate a system of patient safety initiatives within various health care facilities, agencies, and other groups. In Maryland, a similar governmental initiative does not exist. The Maryland Patient Safety Coalition has taken steps to collectively review and analyze patient safety issues as they relate to the health care facilities, boards, and associations. Formed by the Delmarva Foundation which in Maryland is the Peer Review Organization for Medicare, the Maryland Patient Safety Coalition is comprised of health care representatives from state agencies, hospitals, long-term care facilities, and provider and professional boards and associations. Meetings are held on a monthly basis and the experience of nationally-recognized health care organizations noted for their patient safety focus is solicited via presentations to the group. In addition, Delmarva held a conference on patient safety (April 2001) in an effort to disseminate current knowledge and performance improvement efforts about patient safety, and to learn from participants what they need, in terms of research knowledge and technical assistance, to develop, implement, and support patient safety initiatives throughout the region. Delmarva also maintains a website featuring quality improvement projects.

In order to be effective, facility specific initiatives must have the full support and cooperation of leadership and staff. Many health care facilities in Maryland have initiated a broad array of patient safety activities that are promoted by executive management. Some of the hospitals, for instance, maintain adverse event reporting systems while others have created task forces to examine issues such as nosocomial infections and medication administration. Many hospitals and long-term care facilities indicated that leadership commits resources to patient safety initiatives within their facilities and that patient safety plans are in force.

B. Identifying and Learning from Errors

IOM Recommendation -

The IOM report recommends a nationwide mandatory reporting system of standardized information on adverse events and encourages voluntary reporting systems. The VA has instituted both an internal mandatory reporting system of adverse events and an external voluntary adverse event and near miss reporting system. Reports made under the voluntary system are confidential and stripped of patient and provider names, dates, times, and

any other identifying factors. The VHA reports that over 3,000 errors were committed over a 19-month period in 1999 with 710 people dying as a result.[44]

In addition, the IOM recommends that Congress pass legislation extending peer review protections to data related to patient safety and quality improvement collected and analyzed internally by health care facilities.

Maryland Survey Results -

Over half of the hospitals that responded to the survey indicate that leadership encourages employees to identify and report adverse events and near misses. Comparatively, a majority of the long term care and behavioral health facilities responding to the survey encourage employees to report events.

Based on the survey results, three hospitals have instituted various types of systems or policy on reporting adverse events. One facility maintains a non-punitive occurrence reporting system while another wrote that medication errors are self-reported. Another hospital has a policy of disclosure of unanticipated outcomes.

Encouraging health care workers to share information about adverse events and near misses can be difficult if certain protections are not enacted. Employees and staff may be reluctant to provide information to a medical review committee for fear that the information could become publicly available and placing the individual's employment status at risk.

In Maryland, qualified immunity is available to most health occupation boards. Essentially, individuals reporting information to a State regulatory board cannot be held civilly liable if the reports are made without malice. Proceedings, records, and files of a medical and dental review committee are protected under confidentiality and peer review protections with certain exceptions. Protections are not granted, however, in the instances of employment ("whistleblower protections") and when information related to an adverse event or near miss is shared between health care workers.

Effective communication between leadership and staff is critical to sharing key information on the organization's goals towards improving patient safety and quality of care and also for creating a learning environment. Some of the long term care facilities and very few of the hospitals responding to the survey use simulation to improve interpersonal communication and team interactions in high-risk settings, while more of the long term care facilities use case studies to illustrate a non-punitive approach to adverse events than the hospitals.

[44] Rhonda L. Rundle. "In the Drive to Mine Medical Data, VHA is the Unlikely Leader" (Vital Signs). The Wall Street Journal. December 10, 2001.

C. Setting Performance Standards and Expectations for Safety

IOM Recommendation -

The IOM recommends that performance standards and expectations for health care organizations and professionals include patient safety goals. In addition, the IOM states that regulators and accrediting agencies should require health care organizations to implement meaningful patient safety programs with defined executive responsibility.

Also worth noting is that the IOM recommends that health professional licensing bodies work in conjunction with certifying and credentialing organizations to develop more effective methods and a cohesive effort to identify unsafe providers and the corrective action taken against them.

Another aspect of patient safety performance standards is reflected in the IOM recommendation stating that professional societies (associations) should make a visible commitment to patient safety by establishing a permanent committee dedicated to safety improvement.

Maryland Survey Results -

In Maryland, DHMH's OHCQ recently requested that hospitals revise their risk management plans to reflect their current patient safety standards and expectations. The actions of the health professional boards and associations can also have an impact on patient safety activities among their members. The IOM proposed that health professional licensing bodies (boards) should periodically reexamine and re-license key providers based on competence and knowledge of safety practices. The Maryland health licensing and accrediting boards maintain this authority; however, no continuing education requirements specific to patient safety currently exist.

The Pharmacy and Nursing Boards are currently undertaking initiatives aimed at improving patient safety among the groups they represent. *The Statewide Commission on the Crisis in Nursing* approved three principles addressing factors that contribute to the nursing shortage and impact on patient safety. The following principles will be presented to the General Assembly and used to advocate for legislation or regulation:

- Mandatory Overtime/Extra Hours - nurses or nursing assistants may not be compelled to work in excess of the predetermined scheduled hours, except in an emergency. Full time is determined by agency policy but would not to exceed 40 hours and part time would be anything less than 40 hours.
- Whistleblower Protection and Remedies - licensed nurses are required to advise their managers in writing regarding unsafe care and potential risks to patients and employees. Under this recommendation, they would be protected from retaliation by their employer when reporting unsafe care activities and working conditions. If the licensed nurse

believes that he/she has suffered retaliation by their employer, the nurse could seek punitive damages in court. A time limit for filing a report will be designated.

- Nurse Participates in Organizational Processes - organizations would be required to implement a process to determine appropriate staffing and adequate resources and to meet the care needs of the patient. Organizations would be required to include direct care nurses in the processes and ongoing monitoring of the process. In the event that the number of nurses is insufficient, each organization must develop a process to identify such situations and specify contingency plans to assure patient and nurse safety.

The *Maryland Board of Nursing* (MBON) is participating in a pilot study with the Maryland Hospital Association (MHA) to determine if a confidential remedial program that assists a licensed nurse who has been recognized as committing a practice or medication error or has a clinical practice concern increases reporting and enhances patient safety. Called the 'Practitioner Remediation and Enhancement Partnership' or PREP program, its focus is to create a program encouraging the Board and employers to serve as advocates for safe nursing practice through early identification of an at-risk nurse; providing a non-punitive alternative to discipline; developing remediation if needed; and identifying at risk patterns of practice. Initially, a nurse is advised of his/her deficiencies, and then an individualized remedial program is developed. The program is monitored for the nurse's improvement in the identified practice areas. An advisory committee was formed to develop the program components and includes a nurse executive, human resources representative, Board of Nursing member, nurse manager, quality assurance representative, MBON staff, MHA representative, and Board attorney.

Through participation in the program, the nurse is able to continue working for the health care entity and eliminate a notice of discipline on his/her license. Other goals of the program are to strengthen the overall practice of the nurses and to identify problems early.

The *Maryland Board of Pharmacy* sponsored a Medication Error Task Force which began in November 1999 to address the issues of medication errors and patient safety. The charge of the Task Force was to recommend strategies to the Board that the Board could use to guide practitioners and pharmacy permit holders "in redesigning medication systems to reduce the incidence and severity of medication errors in Maryland." Three recommendations were made by the Task Force - (1) educational initiatives for consumers and pharmacy practitioners; (2) system-oriented action in response to errors reported to the Board; and (3) requirements for mandatory pharmacy quality assurance programs designed to address medication errors. Currently in Maryland, non-institutional pharmacies are not afforded protection from discoverability for information collected by a pharmacies' quality assurance program.

Proposed regulations that address medication errors have been approved by the Board and published for comment in the November 16, 2001 Maryland Register. The regulations will require pharmacies to provide patients with information on medication errors and require permit holders to ensure that pharmacy staff receive annual education and training on their role and responsibility in preventing medication errors. Under the proposed regulations, a quality assurance program will also be required of all pharmacy permit holders in an effort to initiate a systemic process to identify and reduce errors. The quality assurance program, however, is not afforded the discoverability protections. The Medication Errors Task Force has recommended

that the information captured under the quality assurance program be protected from discoverability. The Board of Pharmacy's Sunset legislation, which will be introduced during the 2002 legislative session, is expected to include a provision that provides protection for pharmacy quality assurance programs.

The *Maryland Board of Physician Quality Assurance* (BPQA) is the state agency with statutory authority to license physicians and other health care providers, such as physician assistants and respiratory care practitioners to practice medicine in Maryland. The BPQA also is authorized to discipline those licensees who violate the Maryland Medical Practice Act. The Maryland law provides that the Board is required to show by "clear and convincing evidence" that a licensee has breached the Medical Practice Act. A thorough investigation of the facts must precede the Board making a charge against a physician or other health care provider.

While the Board does not maintain a patient safety plan, it has implemented several activities related to patient safety. For example, the Board carefully reviews a applicant's education and training history before a license is awarded. Also, a mandatory 'New Physicians Orientation Program' is conducted, covering several issues including patient safety. The Board also has a Physician Rehabilitation Program, operated by the Medical and Chirurgical Faculty of Maryland (Med Chi). Physicians and other licensees who may be impaired due to physical or psychological reasons, including substance abuse, are referred to this program. In addition to establishing qualifications for licensure, the Board is responsible for investigating complaints against licensees. Systems issues identified as contributing to a patient safety event are referred to the OHCQ.

The MHA (Association of Maryland Hospitals and Health Systems) represents 69 hospitals and health systems in Maryland including acute care, specialty and veterans hospitals, chronic, and long-term care facilities. A prominent goal of the MHA is to advance hospitals' efforts to reduce medication errors and improve patient safety by providing tools, guidelines, and education. To this end, the MHA has implemented three patient safety activities. They are (1) a vision for quality in health care in Maryland; (2) the creation and implementation of the MEDSAFE project; and (3) a collaborative effort to measure medication errors with US Pharmacopeia.

In January 1999, MHA adopted a vision for quality in health care. A key component of this vision is continuous improvement in decreasing the frequency of medical errors. The second patient safety initiative, the MEDSAFE project, is a three-year statewide understanding created to reduce medication errors. The project is voluntary and the information is kept confidential with the goal of identifying and sharing best practice models. Initially, the focus of the project was to establish a baseline among Maryland hospitals on internal environments and culture and systems information technology capabilities. The second year of the project entails establishing a set of guidelines for the measurement of medication use errors through the design or adoption of a measurement tool. During the following year, MHA will perform comparative analysis across Maryland hospitals and establish better practice models for the state.

The third MHA patient safety initiative currently underway is a partnership with US Pharmacopeia and MHA's research entity, the Center for Performance Sciences, to explore ways

of measuring medication use processes in acute care hospitals. Part of the research entails collecting better practice models from select hospitals around the country.

D. Implementing Safety Systems in Health Care Organizations

IOM Recommendations –

The IOM recommends that health care organizations and affiliated professionals should make continually improved patient safety a declared and serious aim by establishing patient safety programs with defined executive responsibility. Beginning with a clear vision, the programs should be non-punitive for reporting and analyzing errors, incorporate well-understood safety principles, and establish interdisciplinary team training programs for providers. Also, health care organizations should implement proven medication safety practices.

Maryland Survey Results -

Based on the Maryland patient survey results, representatives from about a majority of the hospitals and over half of the long-term care facilities replied that their facility maintains a patient safety plan. While the details of these plans have not been analyzed, it is assumed that they vary according to the hospital's size, location, and patient mix.

The use of intensivists in ICUs has proven to reduce the number of patient deaths in those settings. The Leapfrog Group includes this practice as one of its standards hospitals must follow. The Group requires that physicians certified in critical care medicine manage ICUs during the day and are available by page at other times. Within Maryland, over half of the hospitals responding to the survey have intensivists managing the ICUs. Relatively few acute care hospitals use computerized physician order entry (3 have fully implemented), simulation training (3 have fully implemented), and bar coding (1 have fully implemented). Among the long-term care facilities, 22% of the respondents have fully implemented computerized physician order entry, four percent use bar coding (fully implemented), and 29% use simulation training (fully implemented).

The VHA has developed a voluntary adverse event reporting system, the Patient Safety Reporting System (PSRS), that maintains the confidentiality of provider and patient identifiers. The PSRS is designed to collect and analyze data on adverse events and near misses that occur within VA facilities.

As part of a safety system, the IOM recommended that health care organizations should implement proven medication safety practices. Bar coding is one example of a safety practice. The VHA has instituted bar coding devices within their hospitals in an effort to reduce medication related complications and deaths. Bar coding matches a patient's id (bracelet) with his/her medication. Most of the acute care hospitals in Maryland responding to the survey do not use bar coding (approximately 89%), however, a small number of acute care hospitals have routine bar coding or are in the process of implementing it to enhance patient safety.

VII. Policy Issues to Consider for Maryland

Systems Issues

Systemic reform, or the improvement of those processes that affect the management of care (not that of an individual provider), has received much attention since the release of the second IOM report, "Crossing the Quality Chasm." The IOM committee recommends private and public purchasers of health care, health care organizations, clinicians, and patients, should together redesign health care processes by focusing on the system that causes errors. Specifically, the report reads - "Patients should be safe from injury caused by the care system." One approach to improving patient care is through evidence-based medicine, or the care processes. The IOM report indicates that a majority of health care services affecting people reflect only 15 to 25 common conditions and that these conditions are mainly chronic. The AHRQ and the NQF, as mentioned earlier, are studying an expansive list of evidence-based practices that will be made public in the near future.[45]

A team-based approach to providing high-quality care is a second example of systemic change. Care that is provided by a multidisciplinary group of caregivers offers the patient an integrated approach to treatment, providing a seamless level of care over time. The Leapfrog Group has recommended specialized physicians to provide care to patients in hospitals' intensive care units (ICUs). According to Leapfrog, studies have shown that the use of intensivists reduce ICU deaths over ten percent.[46]

The use of information technology to improve systems has proven successful in many health care organizations; however, the cost to implement these systems has posed a barrier to many facilities. The Leapfrog Group has encouraged participating health care organizations to implement computer-based physician order entry systems (CPOE) to help reduce the occurrence of medication errors (50% according to Leapfrog).[47] In New York, a coalition of large businesses has agreed to award bonuses to those providers that have instituted CPOEs. The bonuses, in effect, act as a subsidy to the implementation of the system; however, the cost of implementing the system is assumed by the health care facility. While many organizations are very interested in this type of system, the expense of implementation is often fiscally prohibitive. Some facilities have sought to reduce costs by implementing CPOE in stages.

Other means of improving patient safety within a health care environment include patient and provider education. Many errors can be curtailed through educating and empowering the consumer/patient to gain knowledge on the particular clinical subject area affecting that person and by asking questions. Provider training and continuing education coursework specifically addressing patient safety emphasizes the importance to the health care industry of reducing medical errors. Continuing education in patient safety is an important method of educating health care providers.

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[45] Institute of Medicine. Crossing the Quality Chasm: A New Health System for the 21st Century. 2001.
[46] John D. Birkmeyer, M.D., et. al. *Leapfrog Patient Safety Standards: The Potential Benefits of Universal Adoption.* November 2000. Dr. Birkmeyer estimated that ICU physician staffing would save approximately 53,850 lives each year. Approximately 500,000 deaths occur annually in ICUs.
[47] Dagmara Sarudi, "The Leapfrog Effect," Hospital and Health Networks, May 2001.

For any change to take place, the IOM concludes that health care leaders must encourage a culture of patient safety. In order to implement any improvement in the care process, support from management and staff is critical. James Conway of Boston's Dana Farber Cancer Institute and Nancy Wilson, MD, of the VHA have released assessment tools to assist executives in determining the current status of a patient safety culture in their organizations.[48]

Systemic improvements to patient safety may pose a challenge to some facilities because of financial and staffing constraints; however, these efforts have the greatest potential for bringing about broad based improvements in patient safety.

Reporting Systems

Another method used by many states to improve patient safety is the creation of a reporting system. Reporting systems are designed to capture medical errors related to adverse events, near misses, or both. Currently, 15 states have mandatory reporting systems, whereas, only five states plus the District of Columbia have voluntary reporting systems of adverse events. Mandatory systems require the reporting organization, mainly hospitals but also ambulatory surgical facilities and nursing homes, to report certain events usually to a state agency responsible for the licensing and registration of health care facilities. Voluntary systems may have incident reports supplied to a state agency; however, a private organization separate from the state may administer the system.

The first IOM report recommended a state-based mandatory reporting system of adverse events and encouraged a voluntary system of reporting near misses, or those events that do not cause death or serious harm to the patient. Prior to this report, fifteen states had mandatory systems in place, primarily in response to medical malpractice claims, highly publicized tragic events, and a quality of care oversight requirement.[49] According to NASHP, states that have reporting requirements have not systemically determined the impact these programs have on reducing medical errors. The purpose of implementing the reporting systems was primarily oversight of the health care facilities; however, by collecting, analyzing, and assisting the facilities in improving the care processes, it is expected that medical errors are reduced.[50]

Oftentimes, mandatory reporting systems that require facilities to submit data are labeled as 'punitive' to the health care provider. This may not be the intended purpose however. In the event of adverse events occurring within hospitals, or those incidences that cause death or significant harm to the patient, information is usually reviewed by the hospital's medical review committee (“peer review”). If the state requires this type of information to be submitted to the licensing and regulatory agency, certain protections are usually granted, such as removal of the patient’s name and protections from discoverability prior to investigation. Also, some states shield information from public disclosure either through regulations or statues, while other states make the data available to the public. For example, the Massachusetts Department of Health

[48] Dagmara Sarudi, "Keeping Patients Safe," Hospital and Health Networks, April 2001.
[49] Jill Rosenthal, Maureen Booth, and Anne Barry. *Cost Implications of State Medical Error Reporting Programs: A Briefing Paper*. National Academy for State Health Policy. May 2001.
[50] Ibid.

requires facilities to report adverse events within a defined time period. If an onsite investigation is warranted, the facility's narrative report and statement of deficiencies are available to the public. Also, New York does not publicly disclose information regarding a facility's adverse event report prior to an investigation. If an investigation is conducted, the hospital's initial report and the results of the investigation are publicly available, with some peer review protection granted (patient and provider identifiers are redacted). New York releases hospital-specific aggregate data and findings from their Department of Health Activities.

Some states, national organizations, as well as the Veterans Administration, have instead instituted a voluntary system of reporting errors, whereby the adverse event or near miss is not required to be submitted to the collecting organization and no follow-up is conducted to require changes to underlying problems that may be found. The purpose of a voluntary system is to encourage reporting of events. It is claimed that if a health care practitioner fears retribution for his/her mistakes, that person will not be forthcoming with information that could prevent the error from occurring in the future.

Modeled after the aviation industry's reporting system, the VHA Patient Safety Reporting System is voluntary and confidential. Adverse events and near misses are captured and provider and patient identifiers are not revealed. The projected was implemented in May 2000 and cost $8.2 million.

Resources

The resources expended to create programs, whether systemic or reporting systems, can be great. Researchers under contract with The Leapfrog Group has estimated the financial cost to implement their recommended programs – CPOE, intensivists, and evidence-based referrals, for each project costing varying amounts depending on the size of the hospital and the adequacy of its system to implement the improvement.

For example, Leapfrog researchers estimated that the implementation costs for a CPOE-system could range from approximately $496,000 to almost $15 million depending upon the degree of sophistication of the hospital's computer information system (CIS).[51] A hospital's CIS that is CPOE-enabled will, in turn, cost the hospital less compared to a system that requires replacement. In New York, hospital executives speculate that CPOEs cost from $5 million to $60 million to implement depending on the size of the hospital and degree of CIS sophistication.[52]

As noted by Leapfrog, many studies indicate that CPOE, as well as specialized ICU physicians and volume standards, contribute to direct savings. These savings can be realized over time. CPOE is claimed to lead to fewer medication errors and fewer related adverse drug events along with a greater use of clinical pathways and gains in clinical efficiency. These savings net hospitals thousands of dollars every year.

[51] John D. Birkmeyer, M.D. et. al.. *Economic Implications of the Leapfrog Safety Standards.* June 2001.
[52] Milt Freudenheim. "Companies Start Fund to Reward Hospitals for Better Care." The New York Times. October 18, 2001.

Hiring intensivists in hospital ICUs range from $505,000 to almost $400,000 based upon the number of ICU beds. Savings are projected to range from $771,000 to almost $4 million. The benefits come from more appropriate ICU admissions, reduced ICU and hospital length of stay, and reduced ancillary costs.[53]

The initial outlay for these systemic improvements is likely to be borne by the hospitals and then passed along to insurers. Unique to Maryland, there are several opportunities through the regulatory system to encourage systemic change, such as the rate-setting system, the performance evaluation projects, or the Certificate of Need program.

The costs for a state to implement mandatory reporting systems for the collection of adverse event data had been reviewed by NASHP.[54] The number of full-time equivalents, or FTEs, required for the administration and investigation of incidents is five to seven. The costs for systems design and maintenance is approximately $50,000 to $275,000, in addition to $200,000 to $675,000 for data analyses and validation (in-house and contractual). Funding sources include state resources, such as licensure fees and fines, general funds, and legislative grants.

The Veterans Administration's voluntary reporting system will span three years and cost $8.2 million dollars to implement within the 172 medical centers.

Studies have not been conducted on the costs of programs collecting only 'near miss' information.

Legal Issues

Numerous legal issues impact the development of a patient safety system especially with regard to any mandatory or voluntary reporting systems. There is an inherent tension between the need for accountability and the desire for quality improvement; an appropriate balance must be found. On one hand, if accountability is over-emphasized and no information is protected against public disclosure, then the fear of legal discoverability, litigation, or medical malpractice could contribute to the underreporting of adverse medical events to the detriment of improving the health care system. On the other hand, proponents of disclosure of adverse event information consider public accountability to be an integral requirement for ensuring that health care providers and facilities maintain safe practices and that those injured by adverse events have the opportunity for just compensation.[55] Some observers argue in favor of alternative legal approaches that could be adopted that would diminish the fear of personal liability and promote

[53] John D. Birkmeyer, MD. *Economic Implications of the Leapfrog Safety Standards*. June 2001.
[54] Jill Rosenthal, Maureen Booth, and Anne Barry. "Cost Implications of State Medical Error Reporting Programs: A Briefing Paper." National Academy for State Health Policy. May 2001.
[55] Numerous articles on legal liability, public disclosure, and litigation have been written. See David M. Studdert and Troy A. Brennan. "No Fault Compensation for Medical Injuries," JAMA, July 11, 2001; Jill Rosenthal and Maureen Booth. How Safe is Your Health Care. National Academy for State Health Policy, November 2001; Jill Rosenthal, Maureen Booth, Lynda Flowers, and Trish Riley. Current State Programs Addressing Medical Errors, National Academy for State Health Policy, January 2001; Bryan A. Liang, "Risks of Reporting Sentinel Events," Health Affairs, Sept/Oct 2000.

error reporting. Enterprise liability, presumed vicarious liability, and no-fault compensation systems are also suggested as possible replacements to the current liability system.[56]

Within the current liability system, a number of different mechanisms can be utilized to encourage the reporting of adverse medical events; most of them involve protecting the reporter of the incidents, the recipients of the reported information, or the information that is being reported.[57] Qualified immunity and whistleblower protections provide safeguards for the act of reporting. Disclosure and discoverability issues relate more directly to the act of being directly involved in an adverse event or receiving the reported information.

Qualified Immunity

Generally, qualified immunity means that if a report is made without malice to a State regulatory board, the individual reporting is not civilly liable for the statements in the report. The practical significance of qualified immunity is that when a lawsuit is filed over statements made to a board, the person who made those statements may file an affidavit early in the litigation stating the purpose of the report and the party bringing the lawsuit must counter the affidavit with sufficient facts to constitute a believable case of malice. In most cases, the person bringing the lawsuit cannot meet that burden. In Maryland, statutes governing most health occupation boards include qualified immunity for those reporting to the Board regardless of whether the person reporting is a member of the profession that the Board regulates. Qualified immunity is also extended to certain practitioners who participate in practitioner rehabilitation committees or to anyone who reports information, participates in, or contributes to the function of a medical or dental review committee. In Maryland, nursing, pharmacy and physical therapy personnel must report potential practice violations to their respective boards, and hospitals must report disciplinary actions against physicians to the BPQA. This mandatory reporting to disciplinary boards implicating health care professionals is protected against private litigation by a qualified immunity privilege. Giving qualified immunity to reporters of adverse events can encourage that reporting by providing protections against litigation.

Whistleblower Protections

Whistleblower protections are laws that allow employees to report or testify about employer actions that are illegal, unhealthy or violate specific public policies. Most whistleblower laws have focused on protecting employees who report on improper government and industry actions that are harmful to the environment and the public health. These are protections that provide an employee from being unfairly terminated from employment due to that act of reporting. Maryland has no whistleblower protections for reporting adverse medical

[56] "Enterprise liability" shifts "liability for medical injuries from individual practitioners to responsible organizations…" IOM, To Err is Human, p. 111; W. Sage. "Enterprise Liability and the Emerging Managed Health Care System." 60 -SPG Law & Contemp. Probs. 159 (1997); C. Havighurst. "Vicarious Liability: Relocating Responsibility for the Quality of Medical Care." 26 Am.J.L. & Med. 7 (2000); David M. Studdert and Troy A. Brennan. "No Fault Compensation for Medical Injuries," JAMA, July 11, 2001.

[57] IOM, To Err is Human, P. 127. Jill Rosenthal, Trish Riley, and Maureen Booth. *State Reporting of Medical Errors and Adverse Events: Results of a 50-State Survey*, National Academy for State Health Policy, April 2000.

events. The West Virginia legislature recently passed a patient safety law protecting health care workers from being terminated from their jobs for reporting wrongdoings or abuses. [58]

Disclosure and Discoverability[59]

As noted by the IOM, the protection of reported data pertaining to adverse medical events is crucial to encourage such reporting. They recommend that any reporting done through a mandatory reporting system (which would be for specifically-defined "serious" events) should be subject to disclosure to maintain a level of certain level of accountability in the system. Information reported in a voluntary system (for "near misses" and less injurious adverse events) requires protections for that system to work.

During litigation, information about adverse medical events can be obtained or utilized by those bringing suit in three ways: through a determination that the information is admissible at trial; through pretrial discovery; and as obtained from individuals or organizations who are not named as parties to the lawsuit. It is against these methods for compelling the disclosure of adverse medical event information that any system of protection must be formulated.

Other than the general rules of evidentiary privilege that can protect certain information against disclosure (i.e., attorney-client privilege), there are generally three types of protections that a state can implement to safeguard sensitive information from discovery. These avenues include confidentiality protections, public disclosure protections, and peer/quality review privileges.[60] Confidentiality protects data from being disclosed outside the judicial process. Public disclosure exemptions (i.e., exemptions to the "Open Meeting" or Freedom of Information laws) have generally been utilized when a greater public good is found to override the public's right to know. Peer review and quality review immunities, granted by statute, allow health care organizations to evaluate medical (peer review) and non-medical (quality review) personnel in an open way without fear of disclosure so as to improve the quality of the care being delivered. In addition to the three main protective measures, other protections, such as implementing a system that allows for anonymous reporting or methodologies that de-identify the reported data such as removing the patient's and provider's name, may also be utilized to prevent disclosure.

In Maryland, the proceedings, records, and files of a medical and dental review committee are protected under confidentiality and peer review protections unless either a civil action is brought by a party to the review committee proceedings who claims to be aggrieved by the decision of the review committee or the information considered by the review committee would be subject to discovery and introduction into evidence in a civil trial.[61]

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[58] Damon Adams, "State Error Legislation Gets Mixed Reviews." http://www.ama-assn.org. 7/30/01.
[59] The IOM's report, To Err is Human, provides a detailed analysis of the issues surrounding legal discovery, pp. 109-131.
[60] Rosenthal, et al. Current State Programs Addressing Medical Errors. January 2001. pp. 58-67.
[61] Health Occupations Article, Sections 4-501 and 14-501.

VIII. Preliminary Recommendations

The Patient Safety Initiative in Maryland should build upon existing policies. After reviewing the recent literature on patient safety, surveying major Maryland providers regarding current initiatives in this area, and discussing future directions with members of the Patient Safety Coalition, the Commission recommends the preliminary strategy outlined below to address legislative requirements of House Bill 1274 "Patients' Safety Act of 2001." The Commission recognizes that most of the recommendations in the Institute of Medicine (IOM) report, such as developing mandatory adverse event reporting and creating centers on patient safety to share best practices, are feasible in the sense that they could be implemented. However, limited resources in the State dictate that Maryland's Patient Safety Initiative instead focus on promoting initiatives that can have the greatest impact for the least cost. Following this reasoning, the Commission proposes achieving systemic change first. As noted in the IOM report, few errors are directly caused by individual providers, but rather are a result of a series of systems failures. Elimination of the potential for errors in the system will have the broadest and most lasting effect. Therefore, MHCC proposes the following:

1) The Patient Safety Initiative in Maryland should build upon existing policies and programs currently in place. The MHCC survey of Maryland facilities and organizations revealed there are currently many state agencies, health occupation boards, associations and facilities actively engaged in patient safety initiatives in each of the areas addressed by the IOM report.

2) Systems – The primary focus of the MHCC study should be on how to promote systemic change within institutions to improve patient safety.

   A) Organizational initiatives to improve patient safety should be prioritized, according to cost and effectiveness. Initiatives to be considered should include:

      1) Automation
         a. Computerized physician order entry (CPOE)
         b. Electronic medical records
      2) Communication (labelings, abbreviations, units, etc.)
      3) Pharmaceutical support
      4) Emergency room (ER) and intensive care unit (ICU) staffing – intensivist
      5) Standardization of orders, common equipment, bar coding, etc.
      6) Team training in patient safety
      7) Simplification

   B) Resources for financing major organizational initiatives such as computerized physician order entry (CPOE), should be explored. Research indicates major initiatives such as CPOE can vary in cost per hospital depending on the size of the hospital. Currently, at least 10 of Maryland's forty-seven acute care hospitals have CPOE or are in the

process of implementing it (according to the Maryland Patient Safety Coalition survey). Some hospitals have implemented CPOE in stages to spread the costs. Maryland should take advantage of some of the unique features that exist within the state's health care regulatory structure. The Commission suggests that the MHCC and the HSCRC collaborate to explore ways to encourage hospitals to adopt systemic improvements either through the rate setting system, the Commission's performance evaluation projects (i.e., consumer report cards), and/or the Certificate of Need process.

C) Increased patient safety can be accomplished by focusing on quality improvement programs and processes. Quality improvement initiatives must be shared across facilities and organizations so that knowledge gained in one place can impact other settings and facilities and reduce potential adverse events even before they occur. This feedback mechanism or sharing of "best practices" should be encouraged and be a main objective of any patient safety system.

D) Organizational leadership within all health care facilities should encourage and promote a culture of patient safety.

E) Efforts to promote systemic change should be expanded beyond hospitals to nursing homes, pharmacies, and outpatient care settings.

3) Regulatory Oversight

F) The initial focus of Maryland's efforts should be on strengthening and improving current patient safety programs already ongoing in Maryland hospitals.

G) DHMH should review and revise current risk management regulations to reflect current expectations.

H) DHMH should explore whether definitions and protocols, including lists of events that need to be internally identified and reported, should be standardized.

I) DHMH should explore the possibility of standardizing reporting requirements under the utilization review program to obtain baseline, aggregate data for certain quality of care issues.

4) Maryland Law

A) Maryland statute should be amended to clarify existing reporting protections for civil immunity that are available to all health care professionals reporting to all health occupation boards and medical review committees. Currently, protections that are available to all health care providers for reporting to medical review committees only appear in the statute governing physicians. Protections should be cited in the statutes of all the health occupation boards.

C) Protections against job loss for those reporting system failures or medical errors jeopardizing patient safety to medical review committees should be explored.

5) The Maryland Patient Safety Coalition should continue to meet to focus on patient safety efforts in Maryland health care facilities and provide clear, visible attention to patient safety. The Commission should continue to utilize the services of the Coalition as its "sounding board" for discussing pertinent patient safety issues to be explored during the on-going study of potential recommendations to be included in the final report to the General Assembly in January 2003.

In order to develop final recommendations for Maryland's patient safety initiative, due to the Maryland General Assembly in January 2003, the MHCC will explore several issues over the next twelve months. Input on these issues will be solicited from the Patient Safety Coalition as well as national organizations. Questions to be addressed include the following:

1) Should a non-punitive system (blame-free culture) be developed to encourage voluntary reporting of system failures or "near misses" without legal discovery?

   A) Explore requiring institutions to have internal systems to encourage reporting of near misses and aggregated reporting of systemic problems to a private or non-regulatory organization.
   B) Address issues of discoverability/confidentiality in voluntary reporting.
   C) Consider designation of a private or non-regulatory organization to be a Patient Safety Center. Seek federal funds to set up the Center to disseminate information on near misses, systemic remedies, and best practices.

2) How do staffing issues impact patient safety?

   A) Explore whether links exist between staffing and patient safety.
   B) Investigate whether staffing ratios can be meaningfully quantified as they related to quality of care.

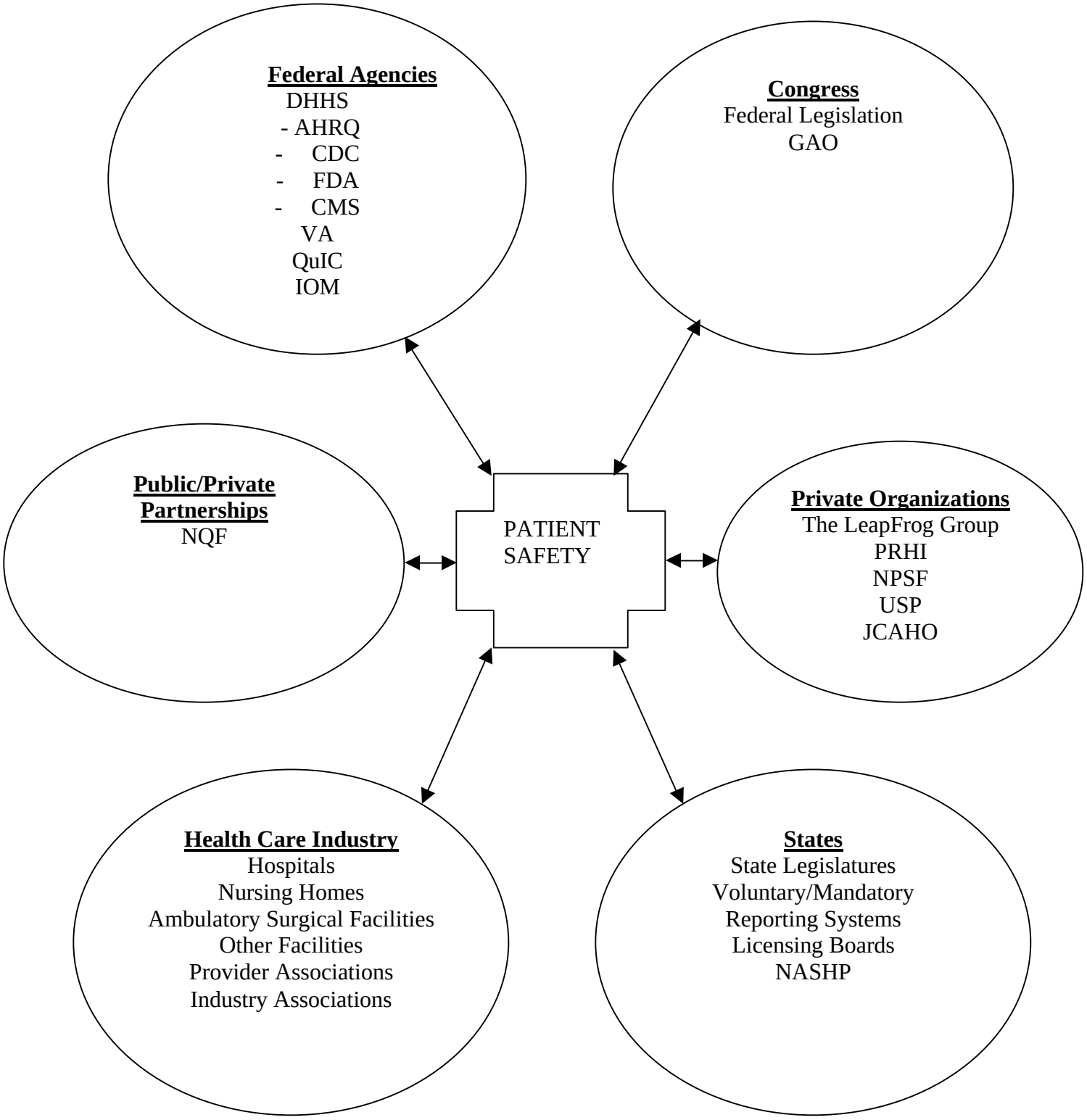
3) Should a patient safety system include the mandatory reporting of serious adverse events?

   A) Should a mandatory reporting system include specific adverse events, such as those defined by the National Quality Forum (NQF)?
   B) Should the state require mandatory reporting from all licensed facilities including assisted living facilities and ambulatory surgery centers? How could reporting requirements be enforced?
   C) Should the adverse events required to be reported be publicly disclosed?

4) Should quality assurance programs currently required in hospitals and nursing homes be mandated for other facilities and in other settings as a condition of licensure?

5) What role should State government have in promoting quality improvement especially in view of the relationship between patient safety and quality improvement? Should the State or a private entity assume the role of providing leadership to promote quality improvement within the health care system?

DIAGRAM A


Federal Agencies
DHHS
- AHRQ
- CDC
- FDA
- CMS
VA
QuIC
IOM
Congress
Federal Legislation
GAO
Public/Private Partnerships
NQF
PATIENT SAFETY
Private Organizations
The LeapFrog Group
PRHI
NPSF
USP
JCAHO
Health Care Industry
Hospitals
Nursing Homes
Ambulatory Surgical Facilities
Other Facilities
Provider Associations
Industry Associations
States
State Legislatures
Voluntary/Mandatory
Reporting Systems
Licensing Boards
NASHP

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Appendix A

Enabling Legislation

HOUSE BILL 1274 (Chapter 318 of 2001)

Patients' Safety Act of 2001

Section 19-139 of the Health General Article

(A) The Commission, in consultation with the Department of Health and Mental Hygiene, shall study the feasibility of developing a system for reducing the incidences of preventable adverse medical events in the state including but not limited to a system of reporting such incidences.

(B) In conducting the study the Commission shall review:

(1) Federal reports and recommendations for identification of medical errors including the most recent report of the Institute of Medicine of the National Academy of Sciences;

(2) Recommendations of national accrediting and quality assurance organizations including the Joint Commission on the Accreditation of Health Care Organizations;

(3) Recommendations of the National Quality Forum:

(4) Programs in other states designed to reduce adverse medical events; and

(5) Best practices of hospitals and other health care facilities.

SECTION 2. And be it further enacted, that, on or before January 1, 2002, the Maryland Health Care Commission issue a preliminary report and, on or before January 1, 2003, issue a final report to the Governor and, subject to §2-1246 of the State Government Article, the House Economic Matters and House Environmental Matters committees, and the Senate Finance Committee on the Commission's recommendations as a result of the study required by this Act.

SECTION 3. And be it further enacted, that this Act shall take effect July 1, 2001.

Appendix B

Minutes from the Maryland Patient Safety Coalition Meetings

June 2001

Tom Schaefer, President of Delmarva, began the meeting by stating that the focus of the group should be to develop an overall approach to patient safety, focusing on addressing reporting activities and actions. As an example, the Massachusetts Coalition created four different work teams to accomplish their goals and it may be a model for the group to explore. One method of accomplishing this could be to map groups, develop measures and recommend actions. Questions to be answered include: (1) What are the patient safety activities in other states as well as our own?; (2) What can we use to fill in our map?; and (3) Where should we align our effort?

Mr. Schaefer suggested six to seven groups to review patient safety issues. One of the key recommendations at a conference Mr. Schaefer attended was to eliminate duplication of efforts. A member attending the meeting recommended that the group examine the current patient safety efforts of Maryland hospitals. Matthew Fitzgerald, the Delmarva Foundation, indicated that there is an important distinction between group error and system failure. Also discussed was funding of patient safety activities. It was noted that an initiative may be recommended even when the funding source is not evident. There are expensive things that can be done, but also activities to be undertaken at a minimal expense.

One action step would be to develop a tool, such as a summary report from the separate groups formed from the Coalition and produce a 'map' of activities. It was recommended that at the next meeting, the group would discuss this to determine see how the 'map' would be completed. Barbara McLean, MHCC, indicated that a report issuing recommendations for developing a system to reduce preventable adverse medical events is due to the Maryland General Assembly in 2003.

July 2001

Mr. Schaefer opened the meeting by stating that the Committee/Coalition should be expanded to meet the mandates of the MHCC. He stated that the Commission is developing a statewide approach to patient safety. Information from an AHRQ sponsored conference, “Beyond State Reporting: Brushing Up on Issues Related to Medical Errors and Patient Safety,” was presented to the group. The conference was sponsored by the National Academy for State Health Policy (NASHP) bringing state representatives together to discuss mandatory reporting initiatives in states and a review of national efforts and recommendations to improve patient safety.

Ms. McLean reviewed the MHCC legislative charge to study and recommend a system to reduce preventable adverse medical events for Maryland. She stated that initiatives would be identified to assist the Maryland legislature with developing a patient safety system or refining the current system. It was recommended that the Hospital Performance Evaluation System (or “report card”) be linked to the patient safety initiative.

Ms. Beverly Miller, The Association of Maryland Hospitals and Health Systems (MHA), reported on one of the association’s activities, the MEDSAFE project. MEDSAFE is a three-year project the MHA is conducting with a limited number of Maryland hospitals, focusing on medication errors. During the first year, information was gathered to gain an understanding about medication use, policies, procedures, delivery systems that are in place, and practices that are effective at reducing errors. A quantitative approach began in December 2000 with a survey of

hospitals to gather information about systems for safe medication delivery. In addition, two self-assessment surveys were distributed to Maryland hospitals to assist hospital leaders in assessing the current status of patient safety activities underway within their facilities and to gain a prospectus as to the improvements required in quality of care. The first survey was distributed in 1999 by the Dana Farber Cancer Institute (Massachusetts) and the second by the American Hospital Association (AHA) and the Veterans Health Administration (VHA) in 2001.

Carol Benner, OHCQ, presented information regarding Maryland law and the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) requirements on patient safety. State regulations requires hospitals to have risk management programs that identify incidents that may be injurious to a patient or that may result in an adverse outcome, require an investigation and evaluation of incidents in a timely manner, take appropriate action to prevent re-occurrence and have a process to address concerns of patients (COMAR 10.07.01.25). Hospitals are protected from civil action in conducting these activities. As part of the risk management plan, hospitals are required to submit an annual report to the DHMH that includes a listing and description of quality of care problems that are reported internally. In addition, DHMH receives complaints on hospitals and investigates them via phone calls and letters along with unannounced and announced visits. DHMH was recently given authority to look beyond the complaint and ask about other patients in the facilities. House Bill 422 (2001) allows DHMH to monitor the hospital until any required corrections are made.

JCAHO requires identification of errors along with an examination of underlying factors, known as a "root cause analysis." Hospitals are encouraged, but not required, to report events. According to Ms. Benner, 1,294 reports were filed over a six-year period out of 7,000 hospitals reporting nationally. Hospitals must submit a root cause analysis for an incidence within 45 days if they choose to report. Following a report, JCAHO surveyors ask for examples of sentinel events during their survey.[62] JCAHO may conduct an unannounced survey if they learn about a sentinel event the hospital did not report.

In addition, JCAHO has developed the "Sentinel Event Alert," an e-mail publication to provide information to facilities. To compliment the sentinel event policy, JCAHO created a toll-free complaint hotline. Federal regulation requires that hospitals have a complaint system and make patients aware of complaint procedures.

Lou Diamond, Vice President and Medical Director of The MEDSTAT Group, presented a hospital web-based Patient Safety Assessment Organizational Tool based on an eight step program: (1) educate leadership; (2) develop leadership consensus; (3) perform assessment of current management strategy to reduce errors; (4) design a better program to reduce errors; (5) define barriers to the program; (6) ask senior management to recommit resources; (7) implement program; and (8) monitor results. The purpose of the Tool is to raise awareness of patient safety, provide a diagnostic snapshot, and initiate a comprehensive approach.

[62] JCAHO defines a sentinel event as " ... injury specifically includes an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. injury specifically includes loss of limb or function. The phrase, "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "sentinel" because they signal the need for immediate investigation and response." JCAHO "Facts about Patient Safety." http://www.jcaho.org/ptsafety_frm.html

Mr. Diamond described MEDSTAT's product offerings as follows: a standards/best practices self-assessment tool administered though the Internet; and off-site review of a defined set of patient safety policies and procedures including a one day on-site review of compliance with processes; and an off-site review of the patient safety policies and procedures along with a two-day on-site review of compliance with policies. Interventions vary according to stage of readiness and willingness to change. Hospitals can use the information to self-improve and in marketing efforts.

Mr. Schaefer stated the assessment tool could provide Maryland with benchmark data and give hospitals a stimulus for improvement. He recommended that Delmarva fund the assessments with the endorsements of the MHA. Participation would be voluntary and would require a single visit. Hospitals may be revisited in one year, or at anytime. The group recommended that the assessments be offered to all 77 Maryland hospitals rather than limiting them to the 47 acute care facilities. It was also suggested that consideration be given to conducting follow-up interviews at a sample of hospitals.

August 2001

During this meeting, Vahe Kazandjian, President, Center for Performance Sciences, Senior Vice President, MHA, gave a presentation on MHA's MEDSAFE project. The MEDSAFE project is a descriptive and quantitative approach to establishing a baseline among Maryland hospitals on internal environments and culture; systems information technology capabilities; provider propensity to "challenge the routine;" and institutional readiness for external accountability. The project is voluntary and the information is kept confidential with the goal of identifying and sharing best practice models.

Based on the first year's data (13 hospitals), a summary of information was presented on accountability, the measurement system used to collect patient safety data, hospital success stories, and recommendations for a statewide initiative to educate hospital leaders and governance on the importance of patient safety and measurement.

Discussion was held regarding the establishment of a baseline of patient safety activities in Maryland. Points made were to identify and understand culture; identify essentials; and an accountability model. The consensus of the group is the next step is to determine the tool. The assessment is just one stage of this process. Ms. Miller stated that the group needs to coordinate activities between the MHA and DHMH. Ms. Benner said that it is timely to examine the Maryland regulations governing patient safety. Ms. Beverly Collins, Delmarva, said this is a great opportunity to come together and update the regulations and legislation.

September 2001

A presentation on the Maryland Board of Pharmacy Initiatives in Medication Errors was presented by Jeanne Furman, R.Ph., Commissioner, Maryland State Board of Pharmacy. A Medication Error Task Force was created to identify and prioritize strategies to guide practitioners and pharmacy permit holders in redesigning medication systems to reduce the incidence and severity of medication errors and to assist the Board of Pharmacy in developing strategies to implement the options the Board selects to address. The Task Force has

recommended to the Board several initiatives to reduce medication errors and improve patient safety. They include: educating consumers and practitioners through pamphlets, newsletters, and the Board's website; mandating continuing education requirements for pharmacists; and using a "systems" approach for medication error complaints. Currently, the Board maintains a non-punitive philosophy for those medication errors that are reported.

Recently, the Pharmacy Board approved regulations that: define "high-alert medication" and a "medication error;" require pharmacies to establish methods to educate patients in preventing medication errors; require pharmacies to ensure that every staff person involved in the delivery of medications receives at least once annually, education regarding preventing medication errors; and require pharmacies to establish and maintain a quality assurance program.

Following the presentation, Mr. Enrique Martinez-Vidal, MHCC, stated that three areas will be explored in the patient safety report in order to provide an overview as to the current federal, national and state activities in patient safety. They are:

- An overview of federal and national efforts and recommendations to improve patient safety (i.e., federal legislation, non-governmental forums);

- An overview of state efforts and recommendations which reduce medical errors (i.e., reporting systems); and

- Maryland activities focusing on patient safety activities within hospitals, nursing homes, industry and provider associations, and state licensing boards

He added that the initial report is due to the Maryland General Assembly January 1, 2002 and final report by January 1, 2003.

Marie McBee, Delmarva, presented an example of the Maryland survey of patient safety initiatives. This survey was adapted from the VHA's survey, An Organization Approach to Patient Safety. Specific feedback from the group was requested. Ms. McBee asked that everyone take some time to look at the survey and make suggestions. Ms. Miller said there is a long tool from VHA which the MHA has endorsed. The American Hospital Association (AHA) has sent this survey to the hospitals. Marie said that this assessment needed to be specific to patient safety activities and that it is intended for hospitals, long-term care facilities, and psychiatric facilities. Recommendations for changes were asked from the group. It was recommended that this survey be distributed at the Leadership Conference (held by MHA and Delmarva). There was discussion of whether the responders should be identified or anonymous.

Ms. Benner added that the OHCQ maintains hospital-specific risk management plans. Some of the group members expressed interest in reviewing the plans. Ms. McBee said that in addition to risk management activities, she would like to collect information about the culture of patient safety in the facilities. She recommended asking the health care groups about the types of activities with which they are involved. There was discussion of risk management plans versus the information about which the group will be asking in the surveys. Ms. Benner stated that risk management plans supply the baseline for patient safety improvement activities.

Mike Preston, MedChi, asked if the survey should include medical staff and if so, what information should be asked. Ms. Miller asked for clarification as to the purpose of the tool (survey). Mr. Martinez-Vidal stated that the HB 1274 stipulates that best practices in health care facilities must be reviewed. It could also be used as an internal tool within the individual organizations. The group was encouraged to assist in the development of the survey.

Mr. Preston shared a proposal developed by MedChi recommending a reconfiguration of the system that regulates physicians (through the Board of Physician Quality Assurance [BPQA]). The recommendation is to implement a system of comprehensive reporting to a quality review agency. Compliance would not be disciplinary and information is kept confidential. He indicated that MedChi is recommending non-punitive interventions and solutions. There was discussion of non-punitive models in other states. Ms. Furman, Board of Pharmacy, asked how physicians are motivated to report to a regulatory board? Mike Preston said the reporting system must be non-punitive and that discoverability is a substantial issue. The responsibility of the BPQA is to have oversight and make the intervention meaningful.

Ms. Donna Dorsey, Board of Nursing, said that nursing board is currently examining a blame-free reporting system. A similar effort was conducted in North Carolina. Ms. Benner said that self-reporting is conducted in hospitals of very serious events. However, these non-punitive reporting systems should not be used to escape accountability. She added that the OHCQ will be issuing *Clinical Alerts* beginning with the potential adverse events associated with the drugs warfarin and Coumadin™ soon.

The meeting concluded with information regarding the MHA Leadership Conference. The conference, held in October, is to include a presentation by Ms. McLean and Mr. Martinez-Vidal on the Commission's hospital performance reporting initiative and the patient safety study.

October 2001

During this meeting, presentations were given by representatives of states with mandatory medical error reporting systems - New York and Massachusetts. The New York Patient Occurrence Reporting and Tracking System (PORTS) was established in 1985 to capture data on adverse events. Definitions for what is to be reported is featured in an includes/excludes list and health facilities are required to report incidences via an interactive internet-based data system. The system is non-punitive when a facility reports an incidence and punitive if the facility does not report. Confidentiality protections are installed to protect the initial adverse event report; however, results from an investigation (if warranted) are publicly available. Public information contains no patient and provider identifiers. Hospital aggregate data are shared with the public.

In Massachusetts, two reporting systems collect data on adverse events, one implemented by the Department of Public Health (DPH) and the other though the Massachusetts Board of Registration in Medicine (BORIM). Both are mandatory reporting systems; however, the reporting requirements for each agency differ slightly. The DPH, as the state regulatory licensing agency, monitors standards and regulations and identifies systems issues based on the data. Its reporting activities are required by regulation. The BORIM reporting system, in contrast, is used

to monitor hospital compliance and is protected by statute.[63] If the DPH conducts an on-site investigation, the information is made public (initial report, facility narrative report, and the statement of deficiencies). Both systems were implemented during the 1980's.

A separate patient safety initiative, The Massachusetts Coalition for the Prevention of Medical Errors, was developed in 1997 and is comprised of public and private agencies, professional associations, researches, insurers, purchasers, payors, and consumers. The goals of the Coalition are to identify and disseminate best practices, institute education and training of health care professionals in patient safety, reduce the regulatory duplication of data collection, and to change the culture of fear of reporting within health care settings to a culture of safety.

Following the presentations, Ms. McLean discussed the consistency of Board statutes. It was noted that the licensing boards in Maryland do not require continuing education requirements in patient safety. Mr. Frederick Ryland, Assistant Attorney General for the MHCC, indicated that the each Board's regulations pertaining to continuing education requirements are broad and could include patient safety.

No Maryland law requires reporting of patient safety violations by physicians, but nursing, pharmacy and physical therapy personnel must report potential practice violations to their respective boards, and hospitals must report disciplinary actions against physicians to the BPQA. Reporting patient safety violations to disciplinary boards implicating health care professionals is protected against private litigation by a qualified immunity privilege.

Also, Mr. Ryland mentioned that Maryland does not maintain "whistleblower protections," or protections from being fired from a job. (Note: Appendix D lists the continuing education requirements and reporting protections designated for each health occupations board within Maryland statute or regulation).

Ms. McBee handed out sample survey tool to be distributed to all Maryland hospitals, nursing homes, licensing boards, and industry and provider associations.

November 2001

Mr. Richard H. Lee, Deputy Secretary for Quality Assurance, Pennsylvania Department of Health, presented information on Pennsylvania's adverse event reporting system. Licensed health care facilities are required to report certain adverse events in compliance with Chapter 51 of Pennsylvania's Health Care Facility Act regulations. Incidents are submitted in writing and are confidential (with the exception of a court order). Investigations are conducted if the Department deems necessary. Adverse events are validated by chart review and analysis of discharge data.

Following Mr. Lee's presentation, Ms. McLean distributed a draft outline for the interim report to the General Assembly and preliminary recommendations. Ms. Benner then discussed OHCQ's role in regulating and licensing Maryland health care facilities. Mr. Benner explained that the OHCQ is the State's licensing authority on behalf of DHMH as well as contracting with the

[63] Paul Barach, MD., MPH and Michael J. Kelly, JD. "Medical Errors and Patient Safety in Massachusetts: What is the Role of the Commonwealth*?" Issue Brief-The Massachusetts Health Policy Forum*. September 2000.

Centers for Medicare and Medicaid Services (CMS) to enforce Medicare and Medicaid regulations for certification to receive federal reimbursement. The OHCQ can conduct facility surveys in the event of a complaint, to monitor compliance or corrective action after CMS, JCAHO, or the State has identified a problem, and to determine compliance with the utilization review, physician credentialing, or risk management/patient safety requirements. Under Maryland law, deficiency statements and plans of corrections are not confidential.

Appendix C

Maryland Health Regulatory Boards
Continuing Education and Reporting Protections

MARYLAND HEALTH REGULATORY BOARDS
CONTINUING EDUCATION AND REPORTING PROTECTIONS

Board	*Continuing Education*	*Reporting Protection*
Acupuncturists	Md. Code, HO § 1A-306(d) COMAR 10.26.02.05F Split between practice of acupuncture and western science and medical practice, including CPR	
Audiologists, Hearing Aid Dispensers & Speech-Language Pathologists	Md. Code, HO § 2-308(e) COMAR 10.41.03.06 Areas of licensure, speech language pathology, audiology, and practice management	Md. Code, HO § 2-207; Ct. & Jud Pro. § 5-703 Qualified Reporting Immunity Md. Code, HO § 2-318(f) Audiologist Rehabilitation Committee Participant Immunity Md. Code, HO § 2-318.1(f) Speech-Language Pathologist Rehabilitation Committee Participant Immunity Md. Code, HO § 2-318.2(f) Hearing Aid Dispenser Rehabilitation Committee Participant Immunity
Chiropractors	Md. Code, HO § 3-308(d) COMAR 10.43.11.03 AIDS/HIV are mandated subjects, otherwise general improvement of professional knowledge and skill regarding chiropractic practice	Md. Code, HO § 3-207; Ct. & Jud Pro. § 5-704 Qualified Reporting Immunity
Dentists & Dental Technicians	Md. Code, HO § 4-205(a)(4),(5) COMAR 10.44.22.05 General standard of enhancing clinical knowledge and ability to treat dental patients	Md. Code, HO § 4-209; Ct. & Jud Pro. § 5-705 Qualified Reporting Immunity; Md. Code, HO § 4-501(f) Dental Review Committee Participant Immunity
Dietitians	Md. Code, HO § 5-308(d) COMAR 10.56.05 Improvement of professional skill relating to practice of dietetics	
Electrologists	Md. Code, HO § 6-309(c)(3)(ii) COMAR 10.53.12 Relevant to theoretical and clinical aspects of electrology	Md. Code, HO § 6-207; Ct. & Jud Pro. § 5-706 Qualified Reporting Immunity
Medical Radiation Technologists	COMAR 10.32.10.09 Relevant to the field of medical radiation technology	Md. Code, HO § 14-412(b) Ct. & Jud Pro. § 5-715 Qualified Reporting Immunity
Morticians	Md. Code, HO § 7-314(c)(4) COMAR 10.29.05 Professional competency in practice of mortuary science	Md. Code, HO § 7-207; Ct. & Jud Pro. § 5-707 Qualified Reporting Immunity

Board	*Continuing Education*	*Reporting Protection*
Nuclear Medicine Technologists	COMAR 10.32.10.09 Relevant to the field of nuclear medicine technology	Md. Code, HO § 14-412(b) Ct. & Jud Pro. § 5-715 Qualified Reporting Immunity
Nurses	Md. Code, HO § 8-312(c) "active nursing practice" hour requirement	Md. Code, HO § 8-505(a) Mandatory Reporting Md. Code, HO § 8-207; Ct. & Jud Pro. §§ 5-708 & 5-709 Qualified Reporting Immunity
Nursing Home Administrators	Md. Code, HO § 9-311(d) COMAR 10.33.01.12 Subjects may include health and safety, local health and safety regulations	Md. Code, HO § 9-207 Ct. & Jud Pro. § 5-710 Qualified Reporting Immunity
Occupational Therapists	Md. Code, HO § 10-311(d) COMAR 10.46.04.05 Competency in occupational theory and practice.	Md. Code, HO § 10-207 Ct. & Jud Pro. § 5-711 Qualified Reporting Immunity
Optometrists	Md. Code, HO § 11-309 COMAR 10.28.02 Improvement of professional skill relating to practice of optometry	Md. Code, HO § 11-209 Ct. & Jud Pro. § 5-712 Qualified Reporting Immunity
Pharmacists	Md. Code, HO § 12-309 COMAR 10.34.18 Any aspect of practice of pharmacy	COMAR 10.34.10.05 Mandatory Reporting Md. Code, HO § 12-207 Ct. & Jud Pro. § 5-713 Qualified Reporting Immunity
Physical Therapists	Md. Code, HO § 13-311(d) COMAR 10.38.08.03B Clinical practice in physical therapy	COMAR 10.38.02.01 Mandatory Reporting Md. Code, HO § 13-208 Ct. & Jud Pro. § 5-714 Qualified Reporting Immunity
Physicians	Md. Code, HO § 14-316 COMAR 10.32.01.09 Broad authority to accept CME which serves to improve knowledge, skills and professional performance of physician for patients, the public, or the profession within basic medicine, clinical medicine, or public health care	Md. Code, HO § 14-412(b) Ct. & Jud Pro. § 5-715 Qualified Reporting Immunity Md. Code, HO §§14-413 & 14-414 Mandated Hospital Reporting Md. Code, HO § 14-501(f) Ct. & Jud Pro. § 5-637 Medical Review Committee Participant Immunity Md. Code, HO § 14-504; Ct. & Jud Pro. § 5-638 Qualified Reporting Immunity for Information Given to Health Care Facilities, Medical Staffs, Professional Societies, Boards and Alternative Health Systems

Board	*Continuing Education*	*Reporting Protection*
Respiratory Care Practitioners	Md. Code, HO § 14-5A13(d) COMAR 10.32.11.11A Relevance to scope of practice of respiratory care	Md. Code, HO § 14-412(b) Ct. & Jud Pro. § 5-715 Qualified Reporting Immunity
Physician Assistants	Md. Code, HO § 15-307(d) COMAR 10.32.03.09A Required course on needs of terminally ill patients	Md. Code, HO § 14-412(b) Ct. & Jud Pro. § 5-715 Qualified Reporting Immunity
Podiatrists	Md. Code, HO § 16-308(d) COMAR 10.40.02.04 Improvement of professional skill relating to practice of podiatry	Md. Code, HO § 16-207 Ct. & Jud Pro. § 5-716 Qualified Reporting Immunity
Professional Counselors and Therapists	Md. Code, HO § 17-309(c)(3)(ii) COMAR 10.58.05.04 Professional competency, increase skills and knowledge, prepare for new roles, and expand science of counseling and therapy theory	
Psychologists	Md. Code, HO § 18-309(d) COMAR 10.36.02 Maintains the professional skill, knowledge or competency of psychologists or expands the practice or prepares psychologists for new roles in practice	Md. Code, HO § 18-205 Ct. & Jud Pro. § 5-717 Qualified Reporting Immunity
Social Workers.	Md. Code, HO § 19-308(d)(3)(ii) COMAR 10.42.06.01B Objective to acquire new knowledge of professionally relevant ideas, increase proficiency in service delivery, refine skills and attitudes	Md. Code, HO § 19-207 Ct. & Jud Pro. § 5-718 Qualified Reporting Immunity

Appendix D

Patient Safety Evidence-based Practices

Listed below are 11 patient safety practices that were considered by the Evidence-based Practice Center at the University of California/Sanford University as "highly proven to work but are not performed routinely in the nation's hospitals and nursing homes."[64]

- Appropriate use of prophylaxis to prevent venous thromboembolism in patients at risk.
- Use of perioperative beta-blockers in appropriate patients to prevent perioperative morbidity and mortality.
- Use of maximum sterile barriers while placing central intravenous catheters to prevent infections.
- Appropriate use of antibiotic prophylaxis in surgical patients to prevent postoperative infections.
- Asking that patients recall and restate what they have been told during the informed consent process.
- Continuous aspiration of subglottic secretions (CASS) to prevent ventilator-associated pneumonia.
- Use of pressure relieving bedding materials to prevent pressure ulcers.
- Use of real-time ultrasound guidance during central line insertion to prevent complications.
- Patient self-management for warfarin (Coumadin™) to achieve appropriate outpatient anticoagulation and prevent complications.
- Appropriate provision of nutrition, with a particular emphasis on early enteral nutrition in critically ill and surgical patients.
- Use of antibiotic-impregnated central venous catheters to prevent catheter-related infections.

[64] Agency for Health Care Research and Quality. "AHRQ Releases New Evidence on Proven Patient Safety Practices." http://www.ahrq.gov/news/press/pr2001/ptsafpr.htm.

Appendix E

Quality Interagency Coordination Task Force (QuIC) Responses and Federal Actions

A Road Map for Action: The Federal Response

This report describes the actions that the QuIC agencies will take to build on current programs and develop new initiatives to reduce errors.

An endorsement of the IOM's goals and strategy development built upon the IOM recommendations and in some cases a step beyond.

I. Create a National Focus to enhance the knowledge base on Patient Safety
II. Set Performance Standards and Expectations for Safety
III. Implement Safety Systems in Health Care Organizations
IV. Additional Federal Actions to Improve Patient Safety

COMPENDIUM OF ACTION ITEMS

I. National Focus and Leadership

Center for Patient Safety

- AHRQ will take immediate action
- CQuIPS will coordinate with and complement other public and private-sector initiatives
- QuIC will coordinate Federal activities
- AHRQ will sponsor a program to educate personel
- QuIC agencies such OPM, HCFA, DoD and VA will demonstrate their national leadership as purchasers
- Federal agencies and other bodies, including AHRQ, FDA, CDC and HCFA will collaborate to provide national leadership

Research Planning

- Hold national summits on medical error and patient safety research
- Establish joint research solicitations for: fundamental research on errors, research on reporting systems, applied research on patient safety
- Develop tools for the public and private sector to support efforts to enhance patient safety including: applications, measures
- Finalize a QuIC research agenda

Identifying and Learning from Errors

- Accountability

- The QuIC will ask the Quality Forum (NQF) to define unambiguously, within 12 months, a set of egregious errors
- HCFA and its QuIC partners will evaluate whether consumers found this information valuable
- Federal agencies in partnership with other organizations will develop options for mandatory reporting systems
- OPM will require that health plans have error reduction plans and will report on its web site

- QuIC will ask the NQF to identify, within 12 months, patient safety practices that institutions should undertake
- FDA will report to the public on the safety of drugs, devices and biologic products
- QuIC proposes that State and Federal mandatory reporting systems, as well as those of private accrediting and other oversight groups be evaluated to determine the ways in which they are helpful in assuring public accountability
- AHRQ will include information on patient safety in the National Quality Report it is developing
- OPM will require that health plans describe patient safety initiatives
- OPM will encourage health plans to annotate Preferred Provider Organization (PPO) directories to indicate which hospitals and physicians' offices use automated information systems
- FDA will improve the safety of transfusions

- Learning from Errors

- The New Center for Quality Improvement and Patient Safety at AHRQ will identify existing State and Federal reporting systems
- QuIC will work with the NQF to develop reporting criteria
- CQuIPS working with the QuIC will describe and disseminate information on characteristics of existing voluntary reporting programs associated with successful error reduction
- Within six months, HCFA, working with a Peer Review Organization (PRO) program
- Federal agencies including the FDA, VA, DoD, CDC, HCFA, and AHRQ, will integrate data from different sources
- By August 2000, the DoD will complete development of a patient safety improvement program based on a reporting system modeled on that of the VA
- VA will establish a voluntary reporting system to supplement its existing mandatory system
- AHRQ in collaboration with other Federal agencies will investigate develop and test strategies to provide effective feedback to clinicians and institutions on methods of improving safety
- Federal agencies will assist health car providers o develop the skills necessary for analyzing adverse events and near misses
- Outreach to Stakeholders: QuIC will develop programs to foster the dissemination of research findings to end users through activities such as AHRQs User Liaison Program
- Patient Safety Clearinghouse: AHRQ will develop a clearinghouse in partnership with other Federal agencies and private-sector organizations to provide an objective source of state-of-art information on patient safety
- AHRQ will initiate a "National Morbidity & Mortality Conference"

- Peer Review Protections

- The QuIC supports the extension of peer review protections to facilitate reporting of errors in a blame-free environment, and will propose considerations of confidentiality that will not undermine current mechanisms to address criminal activity or negligence.

- As part of the development of the national reporting system, appropriate electronic protections (i.e. firewalls and encryption) will be constructed to ensure the confidentiality of the patient involved and the clinician or institution providing the information

II. Setting Performance Standards and Expectations for Safety

- Raising the Standards for Health Care Organizations

- HCFA will use its power as a purchaser and regulator to promote the use of effective error-reduction initiatives in the health care institutions with which it deals
- HCFA will publish regulations this year requiring hospitals participating in the Medicare Program to ongoing medical error reduction programs
- OPM will follow the lead of selected private purchasers to raise the standard for participation by requiring that all health plans with which it contracts seek accreditation from an independent, national accrediting organization that includes evaluation of patient safety and programs to reduce errors in health care.
- In its call letter for the 2001 contract year, OPM will ask health plans to encourage their preferred hospital to use automated prescription systems and other integrated data systems.

- Raising the Standards of Health Care Professionals

The QuIC will:

- Develop and evaluate programs introducing health professionals to errors analysis and the challenges of practicing in a technically complex environment
- Convene a meeting of accrediting, licensing and certifying bodies of the health professions to review information on medical errors
- Collaborate with the Federation of State Medical Boards and other entities to encourage that error reduction and prevention education be a provision for re-licensing of health professionals
- Collaborate in the planning, implementation, and evaluation of a national summit addressing patient safety and medical error reduction programs
- Provide training within QuIC agencies that provide care to encourage use of patient safety information
- Provide technical assistance to State or professional agencies seeking to ensure a basic level of knowledge for health care providers on patient safety issues

- Safe Use of Drugs and Devices

Within 1 year, the FDA will initiate programs to:

- Develop additional standards for proprietary drug names to avoid name confusion
- Develop standards for packaging to prevent dosing and drug mix-ups
- Develop new label standards for drugs, highlight drug-drug interactions, potential dosing errors, and address other common errors
- Implement Phase II pilot study of the Congressionally mandated Medical Product Surveillance Network (MedSUN)
- Intensify efforts to ensure manufacturers' compliance with FDA programs, specifically naming, labeling and packaging

- Provide access to databases linked to health care systems and other sources of adverse-event and marketing data, and link these to existing registries of product users
- Complete the on-line Adverse Reporting Systems (AERS) for drugs and biologics
- Strengthen FDA's analytical and investigative capacities
- Strengthen FDA outreach activities and collaboration with other Government agencies and stakeholders

III. Implementing Safety Systems in Health Care Organizations

- Under the leadership of the CQuIPS, the QuIC will promote, at the executive level, the development and dissemination of evidence-based, best patient-safety practices to provider organizations
- QuIC participants, including HCFA, VA DoD, AHRQ, CDC and FDA, will explore opportunities with private-sector accreditation, purchaser, and provider organizations to develop organization-based, patient-safety models that could be evaluated, and if found effective, disseminated widely
- Through its exemplary patient safety program, VA will continue to scrutinize its care provision for opportunities to improve safety, and develop and expand its reporting system
- VA will invest $47.6 million this year to increase patient safety training for staff
- DoD will invest $64 million FY 2001 to begin implementation of a new computerized medical record system, including an automated order entry system for pharmaceuticals
- Other QuIC direct-care providers will initiate patient safety programs (e.g. HRSA's community health care centers are investigating the most effective programs that can be implemented in their health care delivery systems)
- QuIC member agencies will begin a collaborative project this summer with the Institute for Healthcare Improvement to reduce errors in high-hazard health care delivery settings

IV. Additional Federal Actions to Improve Patient Safety

Building Public Awareness of Medical Errors

- Through the QuICs Enhancing Patient and Consumer Information Working Group, led by OPM and HCFA, Federal agencies will develop and coordinate an information campaign for their constituencies and beneficiaries to increase their awareness of the problem of medical errors and patient safety
- AHRQ will develop generic material for the public on preventing medical errors that Federal agencies can disseminate, reprint, adapt
- The CQuIPS will develop and test patient safety questions for inclusion in the patient survey
- HCFA will conduct research aimed at shaping programs to educate beneficiaries about medical errors
- Within 1 year, FDA will increase collaborative programs with patient and consumer groups regarding patient safety

- FDA will enhance its interactions with the public through meetings with consumer and patient organizations, and through grass-roots informational meetings.
- Patient Safety and reducing medical errors will be featured topic at OPM's Fall 2000 annual health plan conference

Building Purchasers' Awareness of the Problem

- Building on existing relationships with purchasers and business coalitions, such as the National Business Coalition on Health, and the Washington (DC) and Midwest Business Coalitions on Health, DOL, HCFA, OPM and AHRQ will spearhead the QuIC's efforts to promote collaborative programs with other public- and private-sector partners
- At the Federal Benefits Conference, OPM will share information about patient safety with representatives from Federal agencies throughout the Nation

Working with Providers to Improve Patient Safety

- Through the QuIC, Federal agencies will take advantage of existing resources to promote collaborative patient safety programs involving agency constituents, the health professions community, the public, academia, and other stakeholders, such as the American Medical Association, the American Nurses Association, NPSF, NPSP, and the Quality Forum
- VA will develop and run pilot patient safety education programs for medical residents and students

Using Decision-Support Systems and Information Technologies

- AHRQ and CDC will expand research efforts in the area of informatics to include initiatives aimed at developing and evaluating electronic systems to identify, track, and address patient safety concerns
- CQuIPS at AHRQ, along with VA, DoD, FDA and other QuIC member agencies, will evaluate the effectiveness of automated physician order entry systems in hospitals
- DoD, VA and IHS will introduce electronic patient records to offer structured documentation and a common clinical lexicon for practitioners working throughout those systems. The QuIC will encourage other potential Federal participants to do likewise

Using Standardized Procedures, Checklists, and the Results of Human Factors Research

- CDC and FDA will work with the DHHS Advisory Committee on Blood Safety and Availability to help ensure that the highest quality standards are met in blood collection and transfusion
- Within 1 year, FDA will begin working with manufacturers of medical products to explore incorporating standards, including human factors standards, into guidance to ensure that medical products are designed to minimize the chance of errors
- NASA will be invited to become a participant in QuIC activities and bring its understanding and experience in redesigning processes and procedures to enhance sfety

- The QuIC will sponsor an educational program noted in the section on research above to increase the awareness of Federal regulators and policymakers regarding patient safety, human factors, and systems-based improvement
- VA will continue to work with private-sector organizations (e.g. the American Hospital Association and JCAHO) to explore the utility of its comprehensive error analysis and corrective action system

Standards

- The QuIC and its member agencies will ask independent accrediting organizations to demonstrate how they are coordinating and strengthening their patient standards
- AHRQ's CQuIPS through the research agenda articulated above, will develop evidence-based measures that integrate human factors and lessons from other industries
- As with the DQIP measurement set, the QuIC will solicit formal adoption and use by member agencies of common validated and standardized performance measures in the area of error reduction
- QuIC agencies will encourage their private-sector partner organizations to support the implementation of more rigorous safety standards
- The QuIC will work through the Quality Forum, the NPSF, and the NPSP to collaborate with private-sector organizations, industry representatives, academic institutions, and scientific and health care professionals to examine issues related to standards, to test standards of performance measurement, and to establish a set of core standards
- DOL will build on an existing collaboration with the National Association of Insurance Commissioners (NAIC) to exchange information between DOL, the States, employers, plans, and individual patients on medical errors and safe, high-quality health care
- OPM will participate with private-sector organizations in the development of standards and measures, will share QuIC-adopted standards and measures with its health plans, and advocate the use of such standards and measures throughout plan networks
- OPM will also begin collecting performance measurement data from its participating plans, and will make performance information available to beneficiaries of the Federal Employees Health Benefits Program
- Patient safety and reducing medical errors will be a featured topic at OPM's Fall 2000 annual health plan conference

Data Integration

- The QuIC members will work with and support the NQF in its identification of a core set of errors reporting data
- AHRQ, working with its QuIC partners, will identify existing data sets (such as the State mandatory errors reporting data) that can be brought together to enhance the Nation's knowledge and understanding of errors
- OPM will discuss with health plans and preferred provider organizations the development of strategies for focusing disease management programs and integrated data systems on the goal of avoiding medical errors and improving patient outcomes

HCFA, in collaboration with FDA and AHRQ will develop a strategy for incorporating initiatives to increase patient safety into the pharmacy benefit managers program under an expanded Medicare drug benefit.

Appendix F

National Quality Forums
Serious Reportable Adverse Events

National Quality Forum's List of Serious Reportable Adverse Events

Event	Additional Specifications
1. SURGICAL EVENTS	
A. Surgery performed on the wrong body part	Defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.
B. Surgery performed on the wrong patient	Defined as any surgery on a patient that is not consistent with the documented informed consent for that patient.
C. Wrong surgical procedure performed on a patient	Defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.
D. Retention of a foreign object in a patient after surgery or other procedure	Excludes objects intentionally implanted as part of a planned intervention and objects present prior to surgery that were intentionally retained.
E. Intraoperative or immediately post-operative death in an ASA Class I patient	Includes all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out. Immediately post-operative means within 24 hours after induction of anesthesia (if surgery not completed), surgery, or other invasive procedure was completed.
2. PRODUCT OR DEVICE EVENTS	
A. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility	Includes generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination and/or Product
B. Patient death or serious disability associated with the use or function of a device in patient care, in which the device is used or functions other than as intended. .	Includes, but is not limited to, catheters, drains and other specialized tubes, infusion pumps, and ventilators
C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility	Excludes deaths associated with neurosurgical procedures known to be a high risk of intravascular air embolism.

3. PATIENT PROTECTION EVENTS	
A. Infant discharged to the wrong person	Excludes events involving competent adults.
B. Patient death or serious disability associated with patient elopement (disappearance) for more than four hours	
C. Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility	Defined as events that result from patient actions after admission to a healthcare facility. Excludes deaths resulting from self-inflicted injuries that were the reason for admission to the healthcare facility
4. CARE MANAGEMENT EVENTS	
A. Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration)	Excludes reasonable differences in clinical judgment on drug selection and dose.
B. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products	
C. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility	Includes events that occur within 42 days post-delivery. Excludes deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy or cardiomyopathy.
D. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility	
E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinimia in neonates	Hyperbilirubinimia is defined as bilirubin levels >30 mg/dl. Neonates refer to the first 28 days of life.
F. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility	Excludes progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.
G. Patient death or serious disability due to spinal manipulative therapy	

5. ENVIRONMENTAL EVENTS	
A. Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility	Excludes events involving planned treatments such as electric countershock.
B. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances	
C. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility	
D. Patient death associated with a fall while being cared for in a healthcare facility	
E. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility	
6. CRIMINAL EVENTS	
A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist or other licensed healthcare provider	
B. Abduction of a patient of any age	
C. Sexual assault on a patient within or on the grounds of the healthcare facility	
D. Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the healthcare facility	

(Abstracted from The National Quality Forum, "Serious Reportable Events in Patient Safety: A National Quality Forum Consensus Report," http://www.qualityforum.org)

Appendix G

Congressional Action

PATIENT SAFETY RELATED BILLS
INTRODUCED IN CONGRESS
106TH AND 107TH

106TH CONGRESS (1999-2000)	**107TH CONGRESS (2001-2002)**
S. 2038 – Specter "Medical Error Reduction Act of 2000" Introduced: February 8, 2000 Status: referred to Senate subcommittee Summary: Amends the Public Health Service Act to require the Secretary of HHS to make grants to States to establish reporting systems to reduce medical errors	S. 1686 – Kennedy, Kerry, Reid, Clinton "Safe Nursing and Patient Care Act of 2001" Introduced: November 14, 2001 Status: referred to Senate subcommittee Summary: Amends the Social Security Act to provide limitations to the number of hours a nurse is required to work mandatory overtime
S. 2743 – Kennedy, Dodd, Murray "Voluntary Error Reduction and Improvement in Patient Safety Act" Introduced: June 15, 2000 Status: referred to Senate subcommittee Summary: Amends the Public Health Service Act to develop an infrastructure for creating a national voluntary reporting system, prohibits a health care organization from discharging a worker for reporting	S. 1594 – Clinton, Smith, Kennedy, Murray "Nurse Retention and Quality of Care Act of 2001" Introduced: October 30, 2001 Status: referred to Senate subcommittee Summary: Amends the Public Health Service Act to provide programs to improve nurse retention
S. 2738 – Jeffords, Frist, Enzi "Patient Safety and Errors Reduction Act" Introduced: June 15, 2000 Status: referred to Senate subcommittee Summary: Amends the Public Health Service Act to authorize appropriations AHRQ for developing research to determine the causes of medical errors, to develop strategies to reduce them	S. 824 – Graham and Snowe " Medication Errors Reduction Act of 2001" Introduced: May 3, 2001 Status: referred to Senate subcommittee Summary: Directs the Secretary of HHS to establish a program to make grants to eligible entities for the purpose of assisting entities to offset the cost of purchasing, leasing, developing and implementing health care informatics systems
S. 966 – Reid "Patient Safety Act of 1999" Introduced: May 5, 1999 Status: referred to Senate subcommittee Summary: Requires Medicare providers to disclose publicly, staffing and performance in order to promote consumer information and choice	S. 863 – Reid "Patient Safety Act of 2001" Introduced: May 10, 2001 Status: referred to Senate subcommittee Summary: Requires the Secretary of HHS to make public information regarding patient staffing and patient outcomes

H.R. 1288 – Hinchey, Capps, Nadler, Filner, Holden, Bishop, McCarthy, Olver, Serrano, Latourette, Kind, Defazio and Clyburn "Patient Safety Act of 1999" Introduced: March 25, 1999 Status: referred to House subcommittee Summary: Requires Medicare providers to disclose publicly staffing and performance in order to promote improved consumer information	S. 705 – Shumer "Health Information Technology and Quality Improvement Act of 2001" Introduced: April 5, 2001 Status: referred to Senate subcommittee Summary: provides grant program to hospitals, skilled nursing facilities and home health agencies for the establishment of information technology and requires that HHS reimburse these entities for IT systems costs
H.R. 3672 – Morella "Medication Error Prevention Act of 2000" Introduced: February 16, 2000 Status: referred to House subcommittee Summary: Amends Public Health Service Act to medication error information privileged for Federal and State administrative proceedings	H.R. 3238 – Stark, Latourette, Rangel, Barrett, Kleczka, Pomeroy, Lewis, Waxman, Coyne, Schakowsky, etc. "Safe Nursing & Patient Care Act of 2001" Introduced: November 6, 2001 Status: referred to House subcommittee Summary: limits the number of hours a nurse is required to work mandatory overtime
	H.R. 1804 – Hinchey "Patient Safety Act of 2001" Introduced: May 10, 2001 Status: referred to House subcommittee Summary: Requires that providers under Medicare make publicly available nurse staffing and patient outcomes
	H.R. 3292 – Houghton "Medication Errors Reduction Act of 2001" Introduced: November 14, 2001 Status: referred to House subcommittees Summary: Establishes an informatics grant program to hospitals and skilled nursing facilities to encourage facilities to make major information technology upgrades and develop a Medical Technology Advisory Board
	H.R. 2173 - McGovern "Pharmacy Education Aid Act of 2001" Introduced: June 14, 2001 Status: referred to House subcommittee Summary: Includes Pharmacists within the list of national health service corps program

Appendix H

Department of Health and Mental Hygiene, Office of Health Care Quality

The Office of Health Care Quality of the Maryland Department of Health and Mental Hygiene regulates the following health care providers:

Adult Medical Day Care
Assisted Living Programs
Community Mental Health Programs- Mobile Treatment Services
Community Mental Health Programs- Outpatient Mental Health Clinics
Community Mental Health Programs- Psychiatric Rehabilitation Programs
Community Mental Health Programs- Residential Crisis Programs
Community Mental Health Programs- Residential Rehabilitation Programs
Community Mental Health Programs- Respite Care Services
Community Mental Health Programs- Therapeutic Nursery Programs
Comprehensive Rehabilitation Outpatient Facilities
Developmental Disabilities Programs- Day Habilitation Services
Developmental Disabilities Programs- Family and Individual Support Services
Developmental Disabilities Programs- Group Homes
Developmental Disabilities Programs- Intensive Treatment Programs
Developmental Disabilities Programs- Respite Services in State Residential Centers
Freestanding Ambulatory Care Facilities-Ambulatory Surgical Facilities
Freestanding Ambulatory Care Facilities- Birthing Centers
Freestanding Ambulatory Care Facilities- Dialysis Centers
Freestanding Ambulatory Care Facilities- Major Medical Equipment Facilities
Health Care Facilities in Correctional Facilities
Health Maintenance Organizations (HMOs)
Home Health Agencies
Hospice Programs Agencies
Hospitals
Independent Physical Therapists
Job-Related Alcohol and Controlled Dangerous Substances Testing
Limited Service Hospitals
Medical Laboratories- Blood Banks
Medical Laboratories- Cholesterol Testing
Medical Laboratories- Hospitals
Medical Laboratories- Independent Laboratories
Medical Laboratories- Law Enforcement Laboratories
Medical Laboratories- Physician Offices
Medical Laboratories- Proficiency Testing
Medical Laboratories- Tissue Banks
Nursing Homes
Psychiatric Day Treatment Services
Psychiatric Halfway Houses
Residential Service Agencies
Residential Treatment Centers
Substance Abuse Treatment Programs
Therapeutic Group Homes

Appendix I

Maryland Patient Safety Inventory/Survey

Maryland Patient Safety Inventory/Survey

Key Aspect of Safety:	A	B	C	D
Senior leadership* allocates resources to accomplish patient safety** initiatives.				
Senior leadership* directly communicates with medical staff and employees using case studies that illustrate a non-punitive*** approach to adverse events.				
Simulation is used to improve interpersonal communication and team interactions in high-risk settings.				
Leadership encourages employees to identify and report actual errors AND potential for errors during patient care.				
Leadership receives ongoing and timely reports on the frequency and type of medication errors.				
Leadership empowers employees, regardless of rank, to act to avoid adverse events.				
The organization invests in information technology to support patient safety (e.g., computer order entry, decision support).				
The organization informs patients and their families when an adverse event occurs.				
Organization has computerized physician order entry				
Organization has bar coding of patient bracelets and their medication orders (i.e., can double check "right drug to right patient" via bar code).				
ICU managed by physician trained in critical care (hospital only)				
Organization has conducted self assessment and knows of processes that need to be improved to enhance patient safety (e.g., ISMP self-assessment internal survey).				

* Senior Leadership can be defined as CEO, COO, VPMA, VP for Patient Service, or Director of Quality Improvement.

** Patient safety defined as "A type of process or structure whose application reduces the probability of adverse events resulting from exposure to the health care system across a range of diseases and procedures" by Stanford University Evidence-Based Practice Center (EPD).

*** Non-punitive means: "a method of responding to adverse events that do not punish individuals (e.g., firing or suing them) or impose other negative responses (in most cases) aimed at preventing the recurrence of the active error." From To Err Is Human, IOM, p. 56.

*A – There has been **no discussion** around this activity.*

*B – This activity is **under discussion, but there is no implementation within the organization.***

*C – This activity is **undergoing implementation within some or all of the organization.***

*D – This activity is **fully implemented throughout the organization***

Adapted from An Organizational Approach to Patient Safety, VHA, Inc., 2000.

PATIENT SAFETY - HOSPITALS

1. a. Name of facility _____
   b. Address _____
   _____
   c. Number of beds (staffed) _____
   d. Annual discharges _____

2. Please check types of services provided:
   - ❑ Med/Surg
   - ❑ Psych
   - ❑ Rehab
   - ❑ Pediatrics
   - ❑ Other _____

3. Part of a larger system?
   - ❑ Yes, _____ number of hospitals
   - ❑ No

4. Location?
   - ❑ Urban
   - ❑ Suburban
   - ❑ Rural

5. List specific patient safety initiatives implemented by your organization:
   a. _____
   b. _____
   c. _____
   d. _____

   PLEASE ATTACH EXAMPLES/POLICIES, ETC. FOR EACH INITIATIVE.

6. a. Do you have an implemented patient safety plan?
   - ❑ Yes **(PLEASE ATTACH)**
   - ❑ No

6. b. If yes, who spearheaded the development of the plan (i.e., executive leadership *if part of chain/health system;* hospital leadership and/or staff, nursing facility leadership and/or staff; accreditation organizations, professional associations, etc.
   _____

7. a. Comments: _____
   _____
   _____

7. b. Contact (the person we should contact for further information): **OPTIONAL**

Name: _____
Title: _____
Telephone Number: _____
e-mail Address: _____

PATIENT SAFETY - POST-ACUTE/LONG-TERM FACILIITES

1. a. Name of facility _____
   b. Address _____
   _____
   c. Number of beds (staffed) _____
   d. Number of discharges annually _____

2. Please check types of services provided:
   - ❑ Skilled nursing (SNF)
   - ❑ Nursing (Non-SNF)
   - ❑ Long-term care
   - ❑ Specialized _____

3. Structure:
   - ❑ Independent
   - ❑ Part of chain (number of facilities in chain _____)
   - ❑ Ownership type – for profit _____
     not for profit _____

4. Location:
   - ❑ Urban
   - ❑ Suburban
   - ❑ Rural

5. List specific patient safety initiatives implemented by your organization:
   a. _____
   b. _____
   c. _____
   d. _____

   PLEASE ATTACH EXAMPLES/POLICIES, ETC. FOR EACH INITIATIVE.

6. a. Do you have an implemented patient safety plan?
   - ❑ Yes **(PLEASE ATTACH)**
   - ❑ No

6. b. If yes, who spearheaded the development of the plan (i.e., executive leadership *if part of chain/health system;* hospital leadership and/or staff, nursing facility leadership and/or staff; accreditation organizations, professional associations, etc.
   _____

7. a. Comments: _____
   _____

7. b. Contact (the person we should contact for further information): **OPTIONAL**

Name: _____
Title: _____
Telephone Number: _____
e-mail Address: _____

PATIENT SAFETY – STATE LICENSING BOARDS

1. a. Name of licensing board _____
   b. Address _____
   _____
   c. Whom does your board license (i.e., physicians, nurse anesthetists, etc.)?

2. How many practioners does the Board license (FY2001)? _____

3. List specific patient safety* initiatives implemented by your organization:
   a. _____
   b. _____
   c. _____
   d. _____

PLEASE ATTACH EXAMPLES/POLICIES, ETC. FOR EACH INITIATIVE.

* Patient safety means: "a type of process or structure whose application reduces the probability of adverse events resulting from exposure to the health care system across a range of diseases and procedures", by Stanford University Evidence-Based Practice Center (EPD).

4. a. Does your organization have a specific policy or position statement on patient safety?

   - ❑ Yes **(PLEASE ATTACH)**
   - ❑ No

   b. If yes, who developed the policy or statement (i.e., accreditation organizations, professional associations, board members, etc.).
   _____

5. a. Comments: _____
   _____

5. b. Contact (the person we should contact for further information): **OPTIONAL**

   Name: _____
   Title: _____
   Telephone Number: _____
   e-mail Address: _____

PATIENT SAFETY - ASSOCIATIONS

1. a. Name of association _____
   b. Address _____
   _____

   c. Whom does your organization represent?
   _____

2. How many members? _____

3. List specific patient safety initiatives implemented by your organization:
   a. _____
   b. _____
   c. _____
   d. _____

   PLEASE ATTACH EXAMPLES/POLICIES, ETC. FOR EACH INITIATIVE.

4. a. Does your organization have a specific policy position on patient safety?

   - ❑ Yes, **(PLEASE ATTACH)**
   - ❑ No

   b. If yes, who developed the plan (i.e., executive leadership *if part of chain/health system;* hospital leadership and/or staff, nursing facility leadership and/or staff; accreditation organizations, professional associations, etc.
   _____

5. a. Comments: _____
   _____
   _____

5. b. Contact (the person we should contact for further information): **OPTIONAL**

   Name: _____
   Title: _____
   Telephone Number: _____
   e-mail Address: _____